

US3272169 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:21:09

All time stamps listed in this document are displayed in GMT

US3272169

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Participant ID

US3272169

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

US3272169

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:00:53

Generated On: 09 Jun 2021 16:21:09

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 15 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 |
|------------|------|

US3272169

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Apr 2021 15:00:51

Generated On: 09 Jun 2021 16:21:09

| | | |
|---|------------------------|----------------------------------|
| Date of Birth (MMM yyyy) | (b) (6) | 1973 |
| Age | | 47 |
| Age Units | | YEARS |
| Age (Derived) | | 47 |
| Sex | Female | <input checked="" type="radio"/> |
| | Male | <input type="radio"/> |
| Ethnicity | Hispanic or Latino | <input type="radio"/> |
| | Not Hispanic or Latino | <input checked="" type="radio"/> |
| | Not Reported | <input type="radio"/> |
| | Unknown | <input type="radio"/> |
| Race (Check All That Apply) | | |
| White | | True |
| Black | | False |
| Asian | | False |
| American Indian or Alaska Native | | False |
| Native Hawaiian or other Pacific Islander | | False |
| Other | | False |
| If race is Other, specify _____ | | |
| Unknown | | False |
| Not reported | | False |

US3272169

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Apr 2021 15:00:51

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 15 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

Data signed: (b) (4) 09 Apr 2021 15:00:51

Generated On: 09 Jun 2021 16:21:09

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Apr 2021 15:00:52

Generated On: 09 Jun 2021 16:21:09

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | DEPRESSION |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | ARRHYTHMIA (IRREGULAR HEART BEAT) (ATRIAL FIBRILLATION) |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | GASTROESOPHAGEAL REFLUX DISEASE |
| Start date (dd MMM yyyy) | UN UNK 1997 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1997 |
| Start Year (derived) | 1997 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | SEASONAL ALLERGIES |
| Start date (dd MMM yyyy) | UN UNK 1975 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1975 |
| Start Year (derived) | 1975 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | FULL HYSTERECTOMY |
| Start date (dd MMM yyyy) | UN UNK 1999 |
| Start date completely unknown | False |
| 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) | 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 (8)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | ENDOMETRIOSIS |
| Start date (dd MMM yyyy) | UN UNK 1994 |
| Start date completely unknown | False |
| 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) | JAN 1994 |
| Start Year (derived) | 1994 |
| Stop Month and Year (derived) | JAN 1999 |
| Stop Year (derived) | 1999 |

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | ALLERGY TO ASPIRIN |
| Start date (dd MMM yyyy) | UN UNK 1994 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1994 |
| Start Year (derived) | 1994 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | ALLERGY TO CODEINE |
| Start date (dd MMM yyyy) | UN UNK 1990 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1990 |
| Start Year (derived) | 1990 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Form: Medical History (11)

Data signed: (b) (4) 29 Apr 2021 17:49:07

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| | |
|---|--|
| Condition | ALLERGY TO MORPHINE |
| Start date (dd MMM yyyy) | UN UNK 2007 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2007 |
| Start Year (derived) | 2007 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | ALLERGY TO IODINE |
| Start date (dd MMM yyyy) | UN UNK 1994 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1994 |
| Start Year (derived) | 1994 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

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Form: Medical History (14)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | ANTERIOR FUSION 3-7 PSEUDOARTHROSIS (C4-C7) |
| Start date (dd MMM yyyy) | UN UNK 2014 |
| Start date completely unknown | False |
| 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 2014 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2014 |
| Start Year (derived) | 2014 |
| Stop Month and Year (derived) | JAN 2014 |
| Stop Year (derived) | 2014 |

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | LEFT HIP GRAFT |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| Start date completely unknown | False |
| 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 2016 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | JAN 2016 |
| Stop Year (derived) | 2016 |

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | ANTERIOR FUSION 3-7 PSEUDOARTHROSIS (C4-C7) |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| Start date completely unknown | False |
| 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 2016 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | JAN 2016 |
| Stop Year (derived) | 2016 |

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | CATARACT (LEFT EYE) |
| Start date (dd MMM yyyy) | UN UNK 2013 |
| Start date completely unknown | False |
| 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 MAY 2014 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2013 |
| Start Year (derived) | 2013 |
| Stop Month and Year (derived) | MAY 2014 |
| Stop Year (derived) | 2014 |

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | VITREOUS HUMOR (LEFT EYE) (DETAILS UNKNOWN) |
| Start date (dd MMM yyyy) | UN MAY 2020 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | 8 OCT 2020 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | MAY 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | OCT 2020 |
| Stop Year (derived) | 2020 |

US3272169

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | CATARACT SURGERY (LEFT EYE) |
| Start date (dd MMM yyyy) | UN MAY 2014 |
| Start date completely unknown | False |
| 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 MAY 2014 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | MAY 2014 |
| Start Year (derived) | 2014 |
| Stop Month and Year (derived) | MAY 2014 |
| Stop Year (derived) | 2014 |

US3272169

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | OSTEOPOROSIS |
| Start date (dd MMM yyyy) | UN UNK 2012 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2012 |
| Start Year (derived) | 2012 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3272169

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | SUBSTANCE ABUSE |
| Start date (dd MMM yyyy) | UN UNK 1988 |
| Start date completely unknown | False |
| 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 2012 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1988 |
| Start Year (derived) | 1988 |
| Stop Month and Year (derived) | JAN 2012 |
| Stop Year (derived) | 2012 |

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | POST TRAUMATIC STRESS DISORDER |
| Start date (dd MMM yyyy) | UN UNK 1991 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1991 |
| Start Year (derived) | 1991 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | MILD ASTHMA |
| Start date (dd MMM yyyy) | UN UNK 1978 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1978 |
| Start Year (derived) | 1978 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Screening

Form: Medical History (32)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Screening

Form: Medical History (33)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | SYNCOPE |
| Start date (dd MMM yyyy) | 16 JUL 2017 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | 16 JUL 2017 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JUL 2017 |
| Start Year (derived) | 2017 |
| Stop Month and Year (derived) | JUL 2017 |
| Stop Year (derived) | 2017 |

US3272169

Folder: Screening

Form: Medical History (34)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | TONSILLITIS |
| Start date (dd MMM yyyy) | UN UNK 1975 |
| Start date completely unknown | False |
| 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 1975 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1975 |
| Start Year (derived) | 1975 |
| Stop Month and Year (derived) | JAN 1975 |
| Stop Year (derived) | 1975 |

US3272169

Folder: Screening

Form: Medical History (35)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | ADENOIDITIS |
| Start date (dd MMM yyyy) | UN UNK 1975 |
| Start date completely unknown | False |
| 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 1975 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1975 |
| Start Year (derived) | 1975 |
| Stop Month and Year (derived) | JAN 1975 |
| Stop Year (derived) | 1975 |

US3272169

Folder: Screening

Form: Medical History (36)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | CARDIAC ABLATION |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| 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 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 |

US3272169

Folder: Screening

Form: Medical History (37)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | HEART CATH |
| Start date (dd MMM yyyy) | UN UNK 2013 |
| Start date completely unknown | False |
| 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 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 |

US3272169

Folder: Screening

Form: Medical History (38)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | TONSILLECTOMY/ADENOIDECTOMY |
| Start date (dd MMM yyyy) | UN UNK 1975 |
| Start date completely unknown | False |
| 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 1975 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1975 |
| Start Year (derived) | 1975 |
| Stop Month and Year (derived) | JAN 1975 |
| Stop Year (derived) | 1975 |

US3272169

Folder: Screening

Form: Medical History (39)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | TRAUMA SURGERY (POST GUN SHOT WOUND LEFT ARMPIT) |
| Start date (dd MMM yyyy) | UN UNK 1991 |
| Start date completely unknown | False |
| 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 1991 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1991 |
| Start Year (derived) | 1991 |
| Stop Month and Year (derived) | JAN 1991 |
| Stop Year (derived) | 1991 |

US3272169

Folder: Screening

Form: Medical History (40)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | HEART CATH |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| 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 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 |

US3272169

Folder: Screening

Form: Medical History (41)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Condition | BOTOX INJECTION, FACIAL |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| 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 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 |

US3272169

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 15:00:53

Generated On: 09 Jun 2021 16:21:09

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 15 AUG 2020 |
| Time of assessment (00:00-23:59) | 13:55 (24 HR) |
| Vital Signs Date and Time (derived) | 15 AUG 2020 13:55 |
| Height (xxx.x) | 173.5 cm |
| Weight (xxx.x) | 59.7 kg |
| BMI (xxx.x) | 19.83240 kg/m ² |
| BMI units | KG/M2 |
| Temperature (xxx.x) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (xxx) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3272169

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:00:52

Generated On: 09 Jun 2021 16:21:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 AUG 2020

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

US3272169

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 09 Apr 2021 15:00:51

Generated On: 09 Jun 2021 16:21:09

Date of assessment (dd MMM yyyy) 15 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1999

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

US3272169

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Apr 2021 15:00:52

Generated On: 09 Jun 2021 16:21:09

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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3272169

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Apr 2021 15:00:52

Generated On: 09 Jun 2021 16:21:09

| | |
|--|-------|
| Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |
| Resides in high density housing (e.g., high rise apartments with shared entrances or elevators) | False |
| Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes) | False |
| Resides in a single family home (i.e., detached housing) | True |
| Other | False |
| Specify | |

US3272169

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 15 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 |
|------------|--------|

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

What was the date of randomization? (dd MMM yyyy) 15 AUG 2020

What was the participant's randomization number? 104796

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 ☒

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| 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) | 15 AUG 2020 |
| Time of assessment (00:00-23:59) | 13:55 (24 HR) |
| Vital Signs Date and Time (derived) | 15 AUG 2020 13:55 |
| Temperature (xxx.x) | 37 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 69 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 119 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 87 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 15 AUG 2020 |
| Time of assessment (00:00-23:59) | 15:22 (24 HR) |
| Vital Signs Date and Time (derived) | 15 AUG 2020 15:22 |
| Temperature (xxx.x) | 36.5 C |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 64 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 111 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3272169

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 AUG 2020

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

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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) 15 AUG 2020

What was the treatment time? (00:00-23:59) 14:52 (24 HR)

Treatment Date and Time (derived) 15 AUG 2020 14:52

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

US3272169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 15 AUG 2020 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 14:15 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 15 AUG 2020 14:15 |
|------------------------------------|-------------------|

US3272169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 15 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 14:04 | 15 AUG 2020 14:04 |
| Nasopharyngeal Swab 2 | No | | |

US3272169

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 15:16

PC Open Date & Time

15 AUG 2020 15:12

PC Close Date & Time

15 AUG 2020 17:42

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °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 | 15 AUG 2020 21:03 |
| PC Open Date & Time | 15 AUG 2020 18:37 |
| PC Close Date & Time | 16 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

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 ☒

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

16 AUG 2020 15:56

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

17 AUG 2020 21:50

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 23:41

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 22:14

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 21:38

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

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 99.9 °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):

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

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

PC Time Stamp 22 AUG 2020 00:04

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

22 AUG 2020 21:46

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 23:42

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

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

15 AUG 2020 15:17

PC Open Date & Time

15 AUG 2020 15:12

PC Close Date & Time

15 AUG 2020 17:42

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

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

15 AUG 2020 21:05

PC Open Date & Time

15 AUG 2020 18:37

PC Close Date & Time

16 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

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

16 AUG 2020 15:57

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

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

17 AUG 2020 21:50

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

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

18 AUG 2020 23:42

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

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

19 AUG 2020 22:14

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

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

20 AUG 2020 21:38

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 00:04

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 15 AUG 2020 15:17 |
| PC Open Date & Time | 15 AUG 2020 15:12 |
| PC Close Date & Time | 15 AUG 2020 17:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 15 AUG 2020 21:04 |
| PC Open Date & Time | 15 AUG 2020 18:37 |
| PC Close Date & Time | 16 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

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 ☒

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 16 AUG 2020 15:57 |
| PC Open Date & Time | 16 AUG 2020 12:00 |
| PC Close Date & Time | 17 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

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 ☒

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 17 AUG 2020 21:51 |
| PC Open Date & Time | 17 AUG 2020 12:00 |
| PC Close Date & Time | 18 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

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 ☒

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 18 AUG 2020 23:43 |
| PC Open Date & Time | 18 AUG 2020 12:00 |
| PC Close Date & Time | 19 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

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 ☒

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 19 AUG 2020 22:14 |
| PC Open Date & Time | 19 AUG 2020 12:00 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

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 ☒

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US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 AUG 2020 21:39 |
| PC Open Date & Time | 20 AUG 2020 12:00 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

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 ☒

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 AUG 2020 00:05 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 22 AUG 2020 21:46

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

23 AUG 2020 23:42

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

25 AUG 2020 23:56

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

28 AUG 2020 00:30

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

29 AUG 2020 00:35

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

29 AUG 2020 21:39

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 22 AUG 2020 21:46 |
| PC Open Date & Time | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 9 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 23 AUG 2020 23:42 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|------------------------------|
| TIMEPOINT | DAY 10 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 11 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 25 AUG 2020 23:57 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|------------------------------|
| TIMEPOINT | DAY 12 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 13 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 28 AUG 2020 00:31 |
| PC Open Date & Time | 27 AUG 2020 12:00 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 14 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 29 AUG 2020 00:35 |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 15 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 29 AUG 2020 21:39 |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |

US3272169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272169

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272169

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272169

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 16 SEP 2020 |
| Time of assessment (00:00-23:59) | 11:15 (24 HR) |
| Vital Signs Date and Time (derived) | 16 SEP 2020 11:15 |
| Temperature (xxx.x) | 36.4 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 66 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 84 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 65 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 16 SEP 2020 |
| Time of assessment (00:00-23:59) | 12:26 (24 HR) |
| Vital Signs Date and Time (derived) | 16 SEP 2020 12:26 |
| Temperature (xxx.x) | 36.6 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 68 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 81 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 65 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 12:06 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 12:06

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

US3272169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 16 SEP 2020 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 11:20 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 16 SEP 2020 11:20 |
|------------------------------------|-------------------|

US3272169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 16 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:25 | 16 SEP 2020 11:25 |
| Nasopharyngeal Swab 2 | No | | |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

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

98.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp 16 SEP 2020 12:28

PC Open Date & Time 16 SEP 2020 12:26

PC Close Date & Time 16 SEP 2020 14:56

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 16 SEP 2020 21:48 |
| PC Open Date & Time | 16 SEP 2020 15:51 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 99.1 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 17 SEP 2020 21:24 |
| PC Open Date & Time | 17 SEP 2020 12:00 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 99.3 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 18 SEP 2020 23:39 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

19 SEP 2020 21:49

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 98.9 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 20 SEP 2020 23:58 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

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 99.0 °F

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

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

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

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

PC Time Stamp 21 SEP 2020 21:31

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

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 99.0 °F

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

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

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

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

PC Time Stamp 22 SEP 2020 23:19

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

23 SEP 2020 21:59

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 9

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 99.0 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

| | |
|---|-------------------|
| To TREAT pain or fever that has already occurred | True |
| To PREVENT pain or fever from occurring | False |
| PC Time Stamp | 24 SEP 2020 22:32 |
| PC Open Date & Time | 24 SEP 2020 12:00 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 10

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 99.9 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 25 SEP 2020 23:20 |
| PC Open Date & Time | 25 SEP 2020 12:00 |
| PC Close Date & Time | 26 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 11

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 98.7 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 26 SEP 2020 21:31 |
| PC Open Date & Time | 26 SEP 2020 12:00 |
| PC Close Date & Time | 27 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 12

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 98.8 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 27 SEP 2020 23:52 |
| PC Open Date & Time | 27 SEP 2020 12:00 |
| PC Close Date & Time | 28 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 13

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 98.9 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 28 SEP 2020 21:15 |
| PC Open Date & Time | 28 SEP 2020 12:00 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 14

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 98.9 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 29 SEP 2020 22:18 |
| PC Open Date & Time | 29 SEP 2020 12:00 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 15

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 98.7 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 30 SEP 2020 20:03 |
| PC Open Date & Time | 30 SEP 2020 12:00 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 16

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 22:27

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 13:05

PC Open Date & Time

16 SEP 2020 12:26

PC Close Date & Time

16 SEP 2020 14:56

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 21:49

PC Open Date & Time

16 SEP 2020 15:51

PC Close Date & Time

17 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 21:25

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 23:39

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 21:49

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 23:58

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 21:32

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 23:20

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 16 SEP 2020 13:05 |
| PC Open Date & Time | 16 SEP 2020 12:26 |
| PC Close Date & Time | 16 SEP 2020 14:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 16 SEP 2020 21:49 |
| PC Open Date & Time | 16 SEP 2020 15:51 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

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 ☒

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 17 SEP 2020 21:25 |
| PC Open Date & Time | 17 SEP 2020 12:00 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 18 SEP 2020 23:39 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 19 SEP 2020 21:49 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

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 ☒

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 SEP 2020 23:59 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 SEP 2020 21:32 |
| PC Open Date & Time | 21 SEP 2020 12:00 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

166 of 4658

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 SEP 2020 23:20 |
| PC Open Date & Time | 22 SEP 2020 12:00 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 23 SEP 2020 22:00

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

24 SEP 2020 22:32

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

25 SEP 2020 23:21

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

26 SEP 2020 21:31

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

27 SEP 2020 23:52

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

28 SEP 2020 21:16

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

29 SEP 2020 22:18

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

30 SEP 2020 20:03

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

01 OCT 2020 22:27

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(18)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

03 OCT 2020 22:22

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(19)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

04 OCT 2020 23:46

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(20)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(21)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 07 OCT 2020 00:07

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

23 SEP 2020 22:00

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

24 SEP 2020 22:32

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

25 SEP 2020 23:21

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

26 SEP 2020 21:32

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

27 SEP 2020 23:52

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

28 SEP 2020 21:16

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

29 SEP 2020 22:19

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

30 SEP 2020 20:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 OCT 2020 22:27

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

03 OCT 2020 22:22

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

04 OCT 2020 23:46

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

07 OCT 2020 00:07

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

07 OCT 2020 21:04

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 OCT 2020 22:02

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

10 OCT 2020 22:53

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

12 OCT 2020 00:04

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

12 OCT 2020 22:33

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 SEP 2020 22:00

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 SEP 2020 22:32

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 25 SEP 2020 23:21

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 26 SEP 2020 21:32

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 27 SEP 2020 23:53

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 28 SEP 2020 21:16

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

29 SEP 2020 22:19

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

30 SEP 2020 20:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 01 OCT 2020 22:27

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 03 OCT 2020 22:23

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 04 OCT 2020 23:46

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 07 OCT 2020 00:07

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 23 SEP 2020 22:00

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 24 SEP 2020 22:32

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 25 SEP 2020 23:21

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 26 SEP 2020 21:32

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 27 SEP 2020 23:53

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 28 SEP 2020 21:16

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 29 SEP 2020 22:19

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 30 SEP 2020 20:04

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 OCT 2020 22:27

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 03 OCT 2020 22:23

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 04 OCT 2020 23:47

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 07 OCT 2020 00:07

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 23 SEP 2020 22:01 |
| PC Open Date & Time | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 9 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 24 SEP 2020 22:32 |
| PC Open Date & Time | 24 SEP 2020 12:00 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 10 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 25 SEP 2020 23:21 |
| PC Open Date & Time | 25 SEP 2020 12:00 |
| PC Close Date & Time | 26 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 11 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 26 SEP 2020 21:32 |
| PC Open Date & Time | 26 SEP 2020 12:00 |
| PC Close Date & Time | 27 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 12 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 27 SEP 2020 23:53 |
| PC Open Date & Time | 27 SEP 2020 12:00 |
| PC Close Date & Time | 28 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 13

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

No ☐

Yes ☒

PC Time stamp

28 SEP 2020 21:16

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 14 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 29 SEP 2020 22:19 |
| PC Open Date & Time | 29 SEP 2020 12:00 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 15 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 30 SEP 2020 20:04 |
| PC Open Date & Time | 30 SEP 2020 12:00 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 16 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 01 OCT 2020 22:28 |
| PC Open Date & Time | 01 OCT 2020 12:00 |
| PC Close Date & Time | 02 OCT 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|------------------------------|
| TIMEPOINT | DAY 17 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 02 OCT 2020 12:00 |
| PC Close Date & Time | 03 OCT 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 18 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 03 OCT 2020 22:23 |
| PC Open Date & Time | 03 OCT 2020 12:00 |
| PC Close Date & Time | 04 OCT 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 19 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 04 OCT 2020 23:47 |
| PC Open Date & Time | 04 OCT 2020 12:00 |
| PC Close Date & Time | 05 OCT 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|------------------------------|
| TIMEPOINT | DAY 20 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 05 OCT 2020 12:00 |
| PC Close Date & Time | 06 OCT 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 21 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 07 OCT 2020 00:07 |
| PC Open Date & Time | 06 OCT 2020 12:00 |
| PC Close Date & Time | 07 OCT 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|------------------------------|
| TIMEPOINT | DAY 23 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 08 OCT 2020 12:00 |
| PC Close Date & Time | 09 OCT 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 24 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 09 OCT 2020 22:02 |
| PC Open Date & Time | 09 OCT 2020 12:00 |
| PC Close Date & Time | 10 OCT 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 25 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 10 OCT 2020 22:53 |
| PC Open Date & Time | 10 OCT 2020 12:00 |
| PC Close Date & Time | 11 OCT 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 26 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 12 OCT 2020 00:04 |
| PC Open Date & Time | 11 OCT 2020 12:00 |
| PC Close Date & Time | 12 OCT 2020 11:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 27 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 12 OCT 2020 22:33 |
| PC Open Date & Time | 12 OCT 2020 12:00 |
| PC Close Date & Time | 13 OCT 2020 11:59 |

US3272169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272169

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272169

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 OCT 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272169

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 14 OCT 2020 |
|--------------------------|-------------|

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

| | |
|------------|--------|
| Folder OID | VISIT3 |
|------------|--------|

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 14 OCT 2020 |
| Time of assessment (00:00-23:59) | 10:45 (24 HR) |
| Vital Signs Date and Time (derived) | 14 OCT 2020 10:45 |
| Temperature (xxx.x) | 36.7 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 82 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 88 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 62 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3272169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 14 OCT 2020 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 11:10 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 14 OCT 2020 11:10 |
|------------------------------------|-------------------|

US3272169

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| TIMEPOINT | DAY 64 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-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"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 15 OCT 2020 21:35:16 |
| Patient Cloud Open Date & Time | 15 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 19 OCT 2020 23:59 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

22 OCT 2020 00:59:38

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| 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"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-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"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 29 OCT 2020 22:27:09 |
| Patient Cloud Open Date & Time | 29 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 02 NOV 2020 23:59 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| 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 type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 12 NOV 2020 21:10:14 |
| Patient Cloud Open Date & Time | 12 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 16 NOV 2020 23:59 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| TIMEPOINT | DAY 99 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-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"/> 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 21:13:17 |
| Patient Cloud Open Date & Time | 16 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 20 NOV 2020 23:59 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 22:17:26

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-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"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 30 NOV 2020 10:29:20 |
| Patient Cloud Open Date & Time | 30 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 04 DEC 2020 23:59 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

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

07 DEC 2020 19:19:44

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-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"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 14 DEC 2020 07:54:39 |
| Patient Cloud Open Date & Time | 14 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 18 DEC 2020 23:59 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 00:01:57

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 23:38:06

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 06:58:48

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

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

11 JAN 2021 06:47:09

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 07:01:06

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

Date and time of submission

25 JAN 2021 06:59:37

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

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

01 FEB 2021 07:02:23

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-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"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 08 FEB 2021 06:49:40 |
| Patient Cloud Open Date & Time | 08 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 12 FEB 2021 23:59 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 17:10:06

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

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

22 FEB 2021 20:08:43

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-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"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 02 MAR 2021 00:32:15 |
| Patient Cloud Open Date & Time | 01 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 05 MAR 2021 23:59 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 07:01:52

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 09:15:45

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

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

22 MAR 2021 23:03:12

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

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 MAR 2021 07:21:23

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

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

06 APR 2021 10:23:33

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

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

12 APR 2021 17:26:45

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 06:23:43

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 06:32:08

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☒

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

03 MAY 2021 07:18:48

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐
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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐
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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐
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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| TIMEPOINT | DAY 383 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐ 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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 530

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

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

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

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

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

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

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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 551

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 14 FEB 2022 00:01 |
| Patient Cloud Close Date & Time | 18 FEB 2022 23:59 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 558

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| TIMEPOINT | DAY 586 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐ 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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 663

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 20 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 24 JUN 2022 23:59 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

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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 <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 11 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 15 JUL 2022 23:59 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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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 <input type="checkbox"/> |
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐
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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 25 JUL 2022 00:01 |
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|---|-------------------|
| Patient Cloud Close Date & Time | 29 JUL 2022 23:59 |
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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| TIMEPOINT | DAY 733 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 15 AUG 2022 00:01 |
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|---|-------------------|
| Patient Cloud Close Date & Time | 19 AUG 2022 23:59 |
|---|-------------------|

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐ 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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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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 <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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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 <input type="checkbox"/> |
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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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

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Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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 ☐
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 ☐

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| TIMEPOINT | DAY 796 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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

US3272169

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:21:09

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|--------------------------------------|
| Yes | No | 02 MAR 2021 00:32:47 |

US3272169

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272169

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272169

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 JAN 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272169

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 FEB 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272169

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 23 MAR 2021 |
|--------------------------|-------------|

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

| | |
|------------|--------|
| Folder OID | VISIT4 |
|------------|--------|

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Were vital signs assessed? Yes ☐
No ☒

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 ☐
Axillary ☐
Other ☐

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 _____

Height (derived) _____

Weight (derived) _____

US3272169

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 MAR 2021

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

US3272169

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 23 MAR 2021 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 09:15 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 23 MAR 2021 09:15 |
|------------------------------------|-------------------|

US3272169

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:49:07

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272169

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | |
|--|--|
| Date of Contact | 28 SEP 2020 |
| Time of Contact | 08:00 |
| Date and Time of Contact (derived) | 28 SEP 2020 08:00 |
| Type of Contact | <div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div> |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 17 SEP 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|---------------|
| O2 Saturation | ND - Not Done |
|---------------|---------------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|---------------|
| Temperature | ND - Not Done |
|-------------|---------------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

461 of 4658

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

462 of 4658

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 18 SEP 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|---------------|
| O2 Saturation | ND - Not Done |
|---------------|---------------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|---------------|
| Temperature | ND - Not Done |
|-------------|---------------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 19 SEP 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|---------------|
| O2 Saturation | ND - Not Done |
|---------------|---------------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|---------------|
| Temperature | ND - Not Done |
|-------------|---------------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 20 SEP 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|---------------|
| O2 Saturation | ND - Not Done |
|---------------|---------------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|---------------|
| Temperature | ND - Not Done |
|-------------|---------------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 21 SEP 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|---------------|
| O2 Saturation | ND - Not Done |
|---------------|---------------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|---------------|
| Temperature | ND - Not Done |
|-------------|---------------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 22 SEP 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|---------------|
| O2 Saturation | ND - Not Done |
|---------------|---------------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|---------------|
| Temperature | ND - Not Done |
|-------------|---------------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 17:49:03

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| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 23 SEP 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|---------------|
| O2 Saturation | ND - Not Done |
|---------------|---------------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|---------------|
| Temperature | ND - Not Done |
|-------------|---------------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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Generated On: 09 Jun 2021 16:21:09

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

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Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 24 SEP 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|---------------|
| O2 Saturation | ND - Not Done |
|---------------|---------------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|---------------|
| Temperature | ND - Not Done |
|-------------|---------------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 25 SEP 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|---------------|
| O2 Saturation | ND - Not Done |
|---------------|---------------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|---------------|
| Temperature | ND - Not Done |
|-------------|---------------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 26 SEP 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|---------------|
| O2 Saturation | ND - Not Done |
|---------------|---------------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|---------------|
| Temperature | ND - Not Done |
|-------------|---------------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 27 NOV 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|---------------|
| O2 Saturation | ND - Not Done |
|---------------|---------------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|---------------|
| Temperature | ND - Not Done |
|-------------|---------------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 28 NOV 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|-------|
| O2 Saturation | 100 % |
|---------------|-------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 36.8 C |
|-------------|--------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 29 SEP 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|-------|
| O2 Saturation | 100 % |
|---------------|-------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 99.9 F |
|-------------|--------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Form: Symptom Log (13)

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Generated On: 09 Jun 2021 16:21:09

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

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Form: Symptom Log (14)

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Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Form: Symptom Log (14)

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| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 30 SEP 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|-------|
| O2 Saturation | 100 % |
|---------------|-------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 98.7 F |
|-------------|--------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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

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Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 17:49:03

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

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Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 17:49:03

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Symptom Day

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

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Form: Symptom Log (15)

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| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|------------|
| Date | 1 OCT 2020 |
|------|------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 97 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 99.8 F |
|-------------|--------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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

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Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|----------------------|------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 2 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 98.6 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|------------|
| Date | 3 OCT 2020 |
|------|------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 98 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 98.6 F |
|-------------|--------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

Symptom Day

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|------------|
| Date | 4 OCT 2020 |
|------|------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 99 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 98.6 F |
|-------------|--------|

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

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

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| Date of Visit | 28 SEP 2020 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Date of Test | 28 SEP 2020 |
| Type of Test Performed | Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/> |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | |
| CLIA Certified? | Yes <input type="radio"/> No <input type="radio"/> |
| COVID-19 Positive (CSA Programming Field Only) | 0 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| Visit | Was Saliva Collected? | Date of Collection |
|--------|------------------------|--------------------|
| Day 3 | Yes | 30 SEP 2020 |
| Day 5 | Yes | 02 OCT 2020 |
| Day 7 | NA (COVID-19 Negative) | |
| Day 9 | NA (COVID-19 Negative) | |
| Day 14 | NA (COVID-19 Negative) | |
| Day 21 | NA (COVID-19 Negative) | |
| Day 28 | NA (COVID-19 Negative) | |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 28 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SICKD1 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 28 SEP 2020 |
| Time of assessment (00:00-23:59) | 15:18 (24 HR) |
| Vital Signs Date and Time (derived) | 28 SEP 2020 15:18 |
| Height (xxx.x) | 175 cm |
| Weight (xxx.x) | 135.6 lb |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 95 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 66 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3272169

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 SEP 2020

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 27 FEB 2021 |
|--------------------------|-------------|

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

| | |
|------------|---------------|
| Folder OID | UNBLND_DECIDE |
|------------|---------------|

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

Date of updated informed consent (dd MMM yyyy) 27 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 27 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 27 FEB 2021 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 13:15 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 27 FEB 2021 13:15 |
|------------------------------------|-------------------|

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 27 FEB 2021 |
|-------------------------------|-------------|

| | |
|---------------------------------|-------|
| Collection time (00:00 - 23:59) | 13:16 |
|---------------------------------|-------|

| | |
|------------------------------------|-------------------|
| Collection Date and Time (derived) | 27 FEB 2021 13:16 |
|------------------------------------|-------------------|

US3272169

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 27 Nov 2020 16:27:00

Generated On: 09 Jun 2021 16:21:09

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

AEID

Adverse event

GASTROENTERITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

31 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

AEID

Adverse event

GENERALIZED MUSCLE ACHES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

17 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

3 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

AEID

Adverse event

HEADACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|--|
| AEID | USA-US070-2020-MRNA-1273-P30 1000018 |
| Adverse event | RECTAL PROLAPSE |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> 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"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 19 OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 19 OCT 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 24 OCT 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> 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"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

PATIENT DISCLOSED AT DAY
85 PHONE CALL ON 13NOV2020
SHE HAD A RECTAL PROLAPSE
THAT STARTED OCT08SEP2020
WHEN SHE RECEIVED A
ROUTINE COLONOSCOPY AND
THEN HAD A RECTAL
PROLAPSE REPAIR ON
19OCT2020 AND WAS
INPATIENT FROM 19OCT2020
TO 24OCT2020 THEN HAD
COMPLICATIONS AND WAS
INPATIENT AGAIN FROM
05NOV2020 TO 07NOV2020

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|--|
| AEID | USA-US070-2020-MRNA-1273-P30 1000018 |
| Adverse event | RECTAL PROLAPSE REPAIR COMPLICATION DUE TO CONSTIPATION |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 04 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 7 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 5 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 7 NOV 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
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Form: Adverse Events (7)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

PATIENT DISCLOSED AT DAY
85 PHONE CALL ON 13NOV2020
SHE HAD A RECTAL PROLAPSE
THAT STARTED OCT08SEP2020
WHEN SHE RECEIVED A
ROUTINE COLONOSCOPY AND
THEN HAD A RECTAL
PROLAPSE REPAIR ON
19OCT2020 AND WAS
INPATIENT FROM 19OCT2020
TO 24OCT2020 THEN HAD
COMPLICATIONS AND WAS
INPATIENT AGAIN FROM
05NOV2020 TO 07NOV2020.
PARTICIPANT RELEASED HOME
AND HAS HAD SIGNIFICANT
CONSTIPATION UNRELIEVED
BY ENEMA X2 AND MAG
CITRATE X2. READMITTED
05NOV2020 WAS GIVEN MILK
OF MAGNESIUM TWICE DAILY
AND METACLOPRAMIDE
EVERY 6 HOURS PRN.
RESOLUTION OF SYMPTOMS
WITH MULTIPLE BOWEL
MOVEMENTS. SENT HOME
WITH PRESCRIPTION FOR MILK
OF MAGNESIUM AND
POLYETHYLENE GLYCOL.

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|--|
| AEID | |
| Adverse event | NAUSEA |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 4 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 25 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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| | |
|---|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ | |
| Narrative _____ | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | _____ |

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| <hr/> | |
| Narrative | |
| <hr/> | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

AEID

Adverse event

WORSENING OF ABDOMINAL
PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

7 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

AEID

Adverse event

RECTAL BLEEDING

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

2 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|--|
| AEID | USA-US070-2020-MRNA-1273-P30 1000018 |
| Adverse event | HYPONATREMIA |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 5 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 7 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 5 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 7 NOV 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

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Folder: Adverse Events

Form: Adverse Events (13)

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

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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SUBJECT INADVERTENTLY FORGOT TO MENTION THAT PART OF THE REASON FOR HER HOSPITALIZATION FOR THE RECTAL PROLAPSE REPAIR COMPLICATION WAS DUE TO HYPONATREMIA. RECEIVED MEDICAL RECORDS AND REPORTING THAT THIS WAS ALSO THE REASONING FOR THE INPATIENT HOSPITAL STAY FROM 05NOV2020 TO 07NOV2020. 27NOV2021 NOTE READ- MILD, SODIUM 134, RECHECK BMP NEXT WEEK WITH PCP. NO OTHER TREATMENT GIVEN.

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

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|--|
| AEID | |
| Adverse event | VOMITING |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 4 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 25 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|--|
| AEID | |
| Adverse event | DIARRHEA |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 17 SEP 2020 |
| Start time (00:00-23:59) | 08:00 (24 HR) |
| AE start date and time (derived) | 17 SEP 2020 08:00 |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 30 SEP 2020 |
| End time (00:00-23:59) | 08:00 (24 HR) |
| AE End Date and Time (derived) | 30 SEP 2020 08:00 |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ | |
| Narrative _____ | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | _____ |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Apr 2021 17:49:03

Generated On: 09 Jun 2021 16:21:09

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication CELEXA

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION AND ANXIETY

Dose per administration 20

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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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"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2018 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication VRAYLAR

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 1.5

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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Name of Medication VESLCARE

Prophylaxis Yes ☐
No ☒

Indication OVERACTIVE BLADDER

Dose per administration 5

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication LYRICA

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY IN NECK

Dose per administration 50

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------------------------|----------------------------------|
| | 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"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2014 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 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)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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Name of Medication METOPROLOL ER

Prophylaxis Yes ☐
No ☒

Indication ARRHYTHMIA (IRREGULAR
HEART BEAT) ATRIAL
FIBRILLATION

Dose per administration 25

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 2018 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication FLEXERIL

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY IN NECK

Dose per administration 10

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2013 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication PRILOSEC

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication CETRIZINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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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"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN APR 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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Name of Medication VITAMIN E

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 180

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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| | | |
|--|--------------------------|----------------------------------|
| | 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"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN JUN 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 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 (10)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 1000

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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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"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 16 AUG 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 19 AUG 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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Name of Medication PREDNISOLONE ACETATE

Prophylaxis Yes ☐
No ☒

Indication YAG LASER POSTERIOR
CAPSULOTOMY (LEFT EYE)

Dose per administration 1

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

If dose unit is Other, specify DROP

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="radio"/> |
| | 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 checked="" type="radio"/> |
| If route of administration is Other, specify | TOPICAL EYE | |
| Start date (dd MMM yyyy) | 9 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) | 11 OCT 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 4 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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Name of Medication BACTRIM

Prophylaxis Yes ☐
No ☒

Indication GASTROENTERITIS

Dose per administration 800

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------------------------------------|-----------------------|
| | 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"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 20 AUG 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="radio"/> | |
| | No <input checked="" type="radio"/> | |
| If not Ongoing, End date (dd MMM yyyy) | 31 AUG 2020 | |
| Was this medication taken for solicited event? | Yes <input type="radio"/> | |
| | No <input checked="" type="radio"/> | |
| 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 (13)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication FLAGYL

Prophylaxis Yes ☐
No ☒

Indication GASTROENTERITIS

Dose per administration 500

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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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"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 20 AUG 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 31 AUG 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 3 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication COLACE

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION

Dose per administration 50

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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Name of Medication MILK OF MAGNESIA

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION

Dose per administration 4

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

If dose unit is Other, specify TABLESPOONS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

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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"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 3 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 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 (16)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication MIRALAX

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION

Dose per administration 17

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

If dose unit is Other, specify GRAMS

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication DOCULSATE

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION

Dose per administration 500

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

If dose unit is Other, specify

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication REGLAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA/VOMITTING

Dose per administration 10

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

If dose unit is Other, specify

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 ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------------------------|----------------------------------|
| | 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"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 4 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| 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)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication RECTAL PROLAPSE

Dose per administration 800

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

If dose unit is Other, specify

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 ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 08 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| 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 (20)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication MELATONIN

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 5

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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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"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 2 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication SOLU-MEDROL

Prophylaxis Yes ☒
No ☐

Indication IV CONTRAST

Dose per administration 40

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

If dose unit is Other, specify

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 ☐

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------------------------|-------------------------------------|
| | 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 checked="" type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 4 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 4 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication ZOFRAN

Prophylaxis Yes ☒
No ☐

Indication IV CONTRAST

Dose per administration 8

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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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 checked="" type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 4 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 4 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication TRAMODOL

Prophylaxis Yes ☐
No ☒

Indication RECTAL PROLAPSE REPAIR

Dose per administration 50

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 08 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 07 NOV 2020 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication SENNA-DOCUSANE
(PERICOLACE)

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 8.6/50

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

If dose unit is Other, specify

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 14 Apr 2021 19:02:31

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| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | 4 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 7 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication MILD ASTHMA

Dose per administration 2

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

If dose unit is Other, specify

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 ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication MAGNESIUM CITRATE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 300

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

If dose unit is Other, specify

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 ☐

PRODUCTION RELEASE (v12.003

625 of 4658

EAB) (1725)

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

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

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

Name of Medication SODIUM PHOSPHATE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 19/7/197

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

If dose unit is Other, specify G/G/ML

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 ☐

PRODUCTION RELEASE (v12.003

627 of 4658

EAB) (1725)

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 14 Apr 2021 19:02:31

Generated On: 09 Jun 2021 16:21:09

| | | |
|--|--------------------------|-------------------------------------|
| | 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 checked="" type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 01 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 07 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 15:00:51

Generated On: 09 Jun 2021 16:21:09

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 15:00:51

Generated On: 09 Jun 2021 16:21:09

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|---|-----------------|---------------------------------|
| 19 OCT 2020 | RECTAL PROLAPSE REPAIR | Adverse Event | |
| 8 OCT 2020 | YAG LASER POSTERIOR CAPSULOTOMY (LEFT EYE) | Medical History | |
| 4 NOV 2020 | CT IMAGING (ABDOMEN/PELVIS) | Adverse Event | |
| 5 NOV 2020 | CT IMAGING (ABDOMEN/PELVIS) | Adverse Event | |
| 4 SEP 2020 | ESOPHAGOGASTRODUODENOSC OPY (EGD) | Adverse Event | |
| 7 SEP 2020 | CT IMAGING (ABDOMEN/PELVIS) | Adverse Event | |
| 15 OCT 2020 | ELECTROCARDIOGRAM | Other | PRE-OP PHYSICAL |
| 15 OCT 2020 | CHEST X-RAY | Other | PRE-OP PHYSICAL |
| 8 SEP 2020 | ROUTINE COLONOSCOPY | Diagnostic | |

US3272169

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:21:09

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3272169

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:21:09

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 ☐

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|--|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 16/NOV/2020 10:32 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 24/NOV/2020 13:11 |
| 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 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 25/NOV/2020 10:36 |
| 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 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 30/NOV/2020 15:01 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 30/NOV/2020 15:26 |
| 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 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 10/DEC/2020 13:56 |
| 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 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (7)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 16/DEC/2020 11:03 |
| 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 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (8)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 28/DEC/2020 10:12 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (9)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 04/JAN/2021 10:31 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (10)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 22/JAN/2021 15:52 |
| 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 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (11)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 24/JAN/2021 21:29 |
| 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 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (12)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 19/FEB/2021 17:30 |
| 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 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (13)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 26/FEB/2021 09:48 |
| 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 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (15)

Data signed: (b) (4) 29 Apr 2021 17:49:06

Generated On: 09 Jun 2021 16:21:09

| | |
|---|--|
| SAEID | USA-US070-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | ADAM |
| Investigator's Last Name | BROSZ |
| Site Address: Street | 2444 W. FAIDLEY AVE |
| Site Address: City | GRAND ISLAND |
| Site Address: State | NE |
| Site Address: Postal Code | 68803 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 11/MAR/2021 09:07 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

Audit

US3272169 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272169

Form: Participant Creation

Generated On: 09 Jun 2021 16:21:09

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'US3272169' | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Aug 2020 19:29:17 |

US3272169

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:37:44 |

US3272169

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '15 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Aug 2020 19:29:18 |

US3272169

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 15 Aug 2020 20:37:44 |

US3272169

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered 'SCRN' | System | 15 Aug 2020 20:37:44 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered (b) (6) 1973' | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Aug 2020 19:29:19 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '47' | (b) (4), (b) (6) | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered 'YEARS' | System | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered '47' | System | 15 Aug 2020 20:07:12 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Female (F)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | (b) (4), (b) (6) | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[If race is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:09

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:32 |

US3272169

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '15 Aug 2020' | Kayla Flege (b) (4) | 15 Aug 2020 20:07:12 |

US3272169

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered 'Aug 2020' | System | 15 Aug 2020 20:07:12 |

US3272169

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered '2020' | System | 15 Aug 2020 20:07:12 |

US3272169

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:09

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Amendment 2 (2)' | Kayla Flege (b) (4) | 15 Aug 2020 20:07:12 |

US3272169

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | Kayla Flege (b) (4) | 15 Aug 2020 20:07:12 |

US3272169

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 15 Aug 2020 20:07:12 |

US3272169

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:09

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 15 Aug 2020 20:07:12 |

US3272169

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:09

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 15 Aug 2020 20:07:12 |

US3272169

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:09

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Aug 2020 19:29:18 |

US3272169

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:09

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered 'I' | System | 15 Aug 2020 20:07:17 |

US3272169

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | Kayla Flege (b) (4) | 15 Aug 2020 20:07:17 |

US3272169

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:21:09

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:41:00 |

US3272169

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:43:15 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:43:15 |
| Data point term sent to Coder | System | 15 Aug 2020 20:42:09 |
| User entered 'depression' | (b) (4), (b) (6) | 15 Aug 2020 20:41:17 |

US3272169

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 2018' | (b) (4), (b) (6) | 15 Aug 2020 20:41:17 |

US3272169

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:41:17 |

US3272169

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:41:17 |

US3272169

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:41:17 |

US3272169

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:41:17 |

US3272169

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2018' | System | 15 Aug 2020 20:41:17 |

US3272169

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2018' | System | 15 Aug 2020 20:41:17 |

US3272169

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:41:17 |

US3272169

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:41:17 |

US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR RQ: Response to previous query noted as 'updated'. However, the TYPE OF ARRHYTHMIA (eg. Bradyarrhythmia, Supraventricular Arrhythmias, Atrial Fibrillation, etc.) was not specified. Please review and update medical history eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 14:19:19 |
| User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0. | Coder Import (b) (4) | 29 Oct 2020 22:25:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 29 Oct 2020 22:25:52 |
| Query 'Per DM CLR RQ: Response to previous query noted as 'updated'. However, the TYPE OF ARRHYTHMIA (eg. Bradyarrhythmia, Supraventricular Arrhythmias, Atrial Fibrillation, etc.) was not specified. Please review and update medical history eCRF as appropriate.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 28 Oct 2020 15:39:10 |
| Data point term sent to Coder | System | 28 Oct 2020 15:39:07 |
| Coding entries removed. | (b) (4), (b) (6) | 28 Oct 2020 15:38:57 |
| User entered 'ARRHYTHMIA (IRREGULAR HEART BEAT) (atrial fibrillation)' reason for change: Data Entry Error | | 28 Oct 2020 15:38:57 |
| User opened query 'Per DM CLR RQ: Response to previous query noted as 'updated'. However, the TYPE OF ARRHYTHMIA (eg. Bradyarrhythmia, Supraventricular Arrhythmias, Atrial Fibrillation, etc.) was not specified. Please review and update medical history eCRF as appropriate.' (Site from DM). | | 27 Oct 2020 05:22:45 |

US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User closed query 'Per DM CLR: Please specify the type of Arrhythmia (eg, bradyarrhythmia, supraventricular arrhythmias,etc). 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) | 27 Oct 2020 05:22:45 |
| User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Sep 2020 00:22:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Sep 2020 00:22:53 |
| Data point term sent to Coder | System | 22 Sep 2020 00:21:29 |
| Query 'Per DM CLR: Please specify the type of Arrhythmia (eg, bradyarrhythmia, supraventricular arrhythmias,etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6) | 22 Sep 2020 00:20:36 |
| ' answered with 'updated' (Site from DM). | | |
| Coding entries removed. | (b) (4), (b) (6) | 22 Sep 2020 00:20:29 |
| User entered 'ARRHYTHMIA (irregular heart beat)' reason for change: Data Entry Error | | 22 Sep 2020 00:20:29 |
| User opened query 'Per DM CLR: Please specify the type of Arrhythmia (eg, bradyarrhythmia, supraventricular arrhythmias,etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | | 21 Sep 2020 11:11:30 |
| ' (Site from DM). | (b) (4) | |
| User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:43:15 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:43:15 |
| Data point term sent to Coder | System | 15 Aug 2020 20:42:09 |
| User entered 'arrhythmia' | (b) (4), (b) (6) | 15 Aug 2020 20:41:34 |

US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 2018' | (b) (4), (b) (6) | 15 Aug 2020 20:41:34 |

US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:41:34 |

US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:41:34 |

US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:41:34 |

US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:41:34 |

US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2018' | System | 15 Aug 2020 20:41:34 |

US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2018' | System | 15 Aug 2020 20:41:34 |

US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:41:34 |

US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:41:34 |

US3272169

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6) | 11 Nov 2020 14:19:34 |
| ' (Site from DM). | | |
| User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Sensory neuropathy - version MedDRA\23.0. | Coder Import (b) (4) | 29 Sep 2020 13:12:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | (b) (4) | 29 Sep 2020 13:12:52 |
| Data point term sent to Coder | System | 22 Sep 2020 00:23:30 |
| Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6) | 22 Sep 2020 00:23:00 |
| ' answered with 'updated' (Site from DM). | | |
| User entered 'NEUROPATHY IN NECK (Sensory)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 00:22:53 |
| User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | | 21 Sep 2020 11:11:52 |
| ' (Site from DM). | | |
| Data point term sent to Coder | System | 15 Aug 2020 20:42:09 |
| User entered 'neuropathy in neck' | (b) (4), (b) (6) | 15 Aug 2020 20:41:51 |

US3272169

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2013' reason for change: Data Entry Error | Kayla Flege (b) (4) (b) (4) | 25 Sep 2020 19:24:39 |
| User entered 'UN UNK 2014' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Aug 2020 20:42:30 |
| User entered 'un UNK 2018' | | 15 Aug 2020 20:41:51 |

US3272169

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:41:51 |

US3272169

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:41:51 |

US3272169

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:41:51 |

US3272169

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:41:51 |

US3272169

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2013' | System | 25 Sep 2020 19:24:39 |
| User entered 'Jan 2014' | System | 15 Aug 2020 20:42:30 |
| User entered 'Jan 2018' | System | 15 Aug 2020 20:41:51 |

US3272169

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2013' | System | 25 Sep 2020 19:24:39 |
| User entered '2014' | System | 15 Aug 2020 20:42:30 |
| User entered '2018' | System | 15 Aug 2020 20:41:51 |

US3272169

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:41:51 |

US3272169

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:41:51 |

US3272169

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:44:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:44:16 |
| Data point term sent to Coder | System | 15 Aug 2020 20:43:10 |
| User entered 'gastroesophageal reflux disease' | (b) (4), (b) (6) | 15 Aug 2020 20:42:19 |

US3272169

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 1997' | (b) (4), (b) (6) | 15 Aug 2020 20:42:19 |

US3272169

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:42:19 |

US3272169

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:42:19 |
| | | |

US3272169

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:42:19 |

US3272169

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:42:19 |

US3272169

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1997' | System | 15 Aug 2020 20:42:19 |

US3272169

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1997' | System | 15 Aug 2020 20:42:19 |

US3272169

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:42:19 |

US3272169

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:42:19 |

US3272169

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:21:09

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| 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) | 15 Aug 2020 20:44:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:44:16 |
| Data point term sent to Coder | System | 15 Aug 2020 20:43:12 |
| User entered 'seasonal allergies' | (b) (4), (b) (6) | 15 Aug 2020 20:42:44 |

US3272169

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 1975' | (b) (4), (b) (6) | 15 Aug 2020 20:42:44 |

US3272169

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:42:44 |

US3272169

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:42:44 |

US3272169

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:42:44 |

US3272169

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:42:44 |

US3272169

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1975' | System | 15 Aug 2020 20:42:44 |

US3272169

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1975' | System | 15 Aug 2020 20:42:44 |

US3272169

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:42:44 |

US3272169

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:42:44 |

US3272169

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:44:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:44:16 |
| Data point term sent to Coder | System | 15 Aug 2020 20:43:14 |
| User entered 'overactive bladder' | (b) (4), (b) (6) | 15 Aug 2020 20:43:00 |

US3272169

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 2019' | (b) (4), (b) (6) | 15 Aug 2020 20:43:00 |
| | | |

US3272169

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:43:00 |

US3272169

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:43:00 |

US3272169

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:43:00 |

US3272169

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:43:00 |
| | | |

US3272169

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2019' | System | 15 Aug 2020 20:43:00 |

US3272169

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2019' | System | 15 Aug 2020 20:43:00 |

US3272169

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:43:00 |

US3272169

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:43:00 |

US3272169

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:45:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:45:16 |
| Data point term sent to Coder | System | 15 Aug 2020 20:44:15 |
| User entered 'full hysterectomy' | (b) (4), (b) (6) | 15 Aug 2020 20:43:27 |

US3272169

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 1999' | (b) (4), (b) (6) | 15 Aug 2020 20:43:27 |
| | | |

US3272169

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:43:27 |

US3272169

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:43:27 |

US3272169

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 1999' | (b) (4), (b) (6) | 15 Aug 2020 20:43:27 |

US3272169

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 06:29:29 |
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:43:27 |

US3272169

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1999' | System | 15 Aug 2020 20:43:27 |

US3272169

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1999' | System | 15 Aug 2020 20:43:27 |

US3272169

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1999' | System | 15 Aug 2020 20:43:27 |

US3272169

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1999' | System | 15 Aug 2020 20:43:27 |

US3272169

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:46:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:46:17 |
| Data point term sent to Coder | System | 15 Aug 2020 20:45:16 |
| User entered 'endometriosis' | (b) (4), (b) (6) | 15 Aug 2020 20:45:02 |

US3272169

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 1994' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Nov 2020 22:36:30 |
| User entered 'un UNK 1999' | | 15 Aug 2020 20:45:02 |

US3272169

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:45:02 |

US3272169

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:45:02 |

US3272169

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 1999' | (b) (4), (b) (6) | 15 Aug 2020 20:45:02 |
| | | |

US3272169

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:45:02 |

US3272169

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1994' | System | 25 Nov 2020 22:36:30 |
| User entered 'Jan 1999' | System | 15 Aug 2020 20:45:02 |

US3272169

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1994' | System | 25 Nov 2020 22:36:30 |
| User entered '1999' | System | 15 Aug 2020 20:45:02 |

US3272169

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1999' | System | 15 Aug 2020 20:45:02 |

US3272169

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1999' | System | 15 Aug 2020 20:45:02 |

US3272169

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:21:09

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:47:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:47:17 |
| Data point term sent to Coder | System | 15 Aug 2020 20:46:19 |
| User entered 'allergy to aspirin' | (b) (4), (b) (6) | 15 Aug 2020 20:45:19 |

US3272169

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 1994' | (b) (4), (b) (6) | 15 Aug 2020 20:45:19 |

US3272169

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:45:19 |

US3272169

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:45:19 |

US3272169

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:45:19 |

US3272169

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:45:19 |

US3272169

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1994' | System | 15 Aug 2020 20:45:19 |

US3272169

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1994' | System | 15 Aug 2020 20:45:19 |

US3272169

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:45:19 |

US3272169

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:45:19 |

US3272169

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:21:09

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:47:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:47:17 |
| Data point term sent to Coder | System | 15 Aug 2020 20:46:17 |
| User entered 'allergy to codeine' | (b) (4), (b) (6) | 15 Aug 2020 20:45:33 |

US3272169

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 1990' | (b) (4), (b) (6) | 15 Aug 2020 20:45:33 |

US3272169

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:45:33 |

US3272169

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:45:33 |
| | | |

US3272169

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:45:33 |

US3272169

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:45:33 |

US3272169

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1990' | System | 15 Aug 2020 20:45:33 |

US3272169

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1990' | System | 15 Aug 2020 20:45:33 |

US3272169

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:45:33 |

US3272169

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:45:33 |

US3272169

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:47:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:47:17 |
| Data point term sent to Coder | System | 15 Aug 2020 20:46:19 |
| User entered 'allergy to morphine' | (b) (4), (b) (6) | 15 Aug 2020 20:45:52 |

US3272169

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 2007' | (b) (4), (b) (6) | 15 Aug 2020 20:45:52 |

US3272169

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:45:52 |

US3272169

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:45:52 |
| | | |

US3272169

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:45:52 |

US3272169

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:45:52 |

US3272169

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2007' | System | 15 Aug 2020 20:45:52 |

US3272169

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2007' | System | 15 Aug 2020 20:45:52 |

US3272169

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:45:52 |

US3272169

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:45:52 |

US3272169

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:21:09

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Iodine allergy, LLT: Iodine allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:47:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:47:17 |
| Data point term sent to Coder | System | 15 Aug 2020 20:46:17 |
| User entered 'allergy to iodine' | (b) (4), (b) (6) | 15 Aug 2020 20:46:08 |

US3272169

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 1994' | (b) (4), (b) (6) | 15 Aug 2020 20:46:08 |

US3272169

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:46:08 |
| | | |

US3272169

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:46:08 |

US3272169

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:46:08 |

US3272169

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:46:08 |

US3272169

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1994' | System | 15 Aug 2020 20:46:08 |

US3272169

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1994' | System | 15 Aug 2020 20:46:08 |

US3272169

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:46:08 |

US3272169

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:46:08 |

US3272169

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 13:44:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 13:44:36 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:48:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:48:17 |
| Data point term sent to Coder | System | 15 Aug 2020 20:47:19 |
| User entered 'allergy to toradol' | (b) (4), (b) (6) | 15 Aug 2020 20:46:20 |

US3272169

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 1999' | (b) (4), (b) (6) | 15 Aug 2020 20:46:20 |

US3272169

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:46:20 |

US3272169

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:46:20 |
| | | |

US3272169

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:46:20 |

US3272169

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:46:20 |

US3272169

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1999' | System | 15 Aug 2020 20:46:20 |

US3272169

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1999' | System | 15 Aug 2020 20:46:20 |

US3272169

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:46:20 |

US3272169

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:46:20 |

US3272169

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 11:29:35 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 11:29:35 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 21:09:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 21:09:41 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:48:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Aug 2020 20:48:17 |
| Data point term sent to Coder | System | 15 Aug 2020 20:47:20 |
| User entered 'allergy to dilaudid' | (b) (4), (b) (6) | 15 Aug 2020 20:46:41 |

US3272169

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 2019' | (b) (4), (b) (6) | 15 Aug 2020 20:46:41 |

US3272169

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:46:41 |

US3272169

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:46:41 |

US3272169

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:46:41 |

US3272169

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:46:41 |

US3272169

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2019' | System | 15 Aug 2020 20:46:41 |

US3272169

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2019' | System | 15 Aug 2020 20:46:41 |

US3272169

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:46:41 |

US3272169

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 15 Aug 2020 20:46:41 |

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Surgical and medical procedures, HLG: 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) | 23 Nov 2020 13:01:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 23 Nov 2020 13:01:50 |
| User closed query 'Per DM CLR: Please specify the specific location of Fusion 3-7 (ex. Cervical, Lumbar, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6) | 11 Nov 2020 14:21:26 |
| ' (Site from DM). | | |
| 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) | 30 Oct 2020 13:25:06 |
| Data point term sent to Coder | System | 22 Sep 2020 00:24:33 |
| 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 'is in mh as neuropathy in neck' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 00:24:29 |
| Query 'Per DM CLR: Please specify the specific location of Fusion 3-7 (ex. Cervical, Lumbar, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6) | 22 Sep 2020 00:23:55 |
| ' answered with 'updated' (Site from DM). | | |

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User entered 'ANTERIOR FUSION 3-7 PSEUDOARTHROSIS (c4-c7)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 00:23:44 |
| 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) | 21 Sep 2020 11:13:47 |
| User opened query 'Per DM CLR: Please specify the specific location of Fusion 3-7 (ex. Cervical, Lumbar, etc). 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) | 21 Sep 2020 11:13:34 |
| Data point term sent to Coder | System | 11 Sep 2020 21:28:01 |
| User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. (Site from System). | System | 11 Sep 2020 21:27:37 |
| Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. answered with 'this is one procedure' (Site from System). | (b) (4), (b) (6) | 11 Sep 2020 21:27:37 |
| User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. (Site from System). | Coder Import (b) (4) | 17 Aug 2020 16:49:07 |
| Data point term sent to Coder | System | 15 Aug 2020 20:47:21 |
| User entered 'anterior fusion 3-7 pseudoarthrosis' | (b) (4), (b) (6) | 15 Aug 2020 20:47:18 |

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 2014' | (b) (4), (b) (6) | 15 Aug 2020 20:47:18 |

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:47:18 |

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:47:18 |

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 2014' | (b) (4), (b) (6) | 15 Aug 2020 20:47:18 |
| | | |

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:47:18 |

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2014' | System | 15 Aug 2020 20:47:18 |

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2014' | System | 15 Aug 2020 20:47:18 |

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2014' | System | 15 Aug 2020 20:47:18 |

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2014' | System | 15 Aug 2020 20:47:18 |

US3272169

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| 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) | 30 Oct 2020 13:25:07 |
| 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 'fusion is listed in mh' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 00:26:26 |
| 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) | 21 Sep 2020 11:14:06 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone graft, LLT: Bone graft - version MedDRA\23.0. | Coder Import (b) (4) | 17 Aug 2020 23:46:20 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 17 Aug 2020 23:46:20 |
| Data point term sent to Coder | System | 15 Aug 2020 20:48:21 |
| User entered 'left hip graft' | (b) (4), (b) (6) | 15 Aug 2020 20:47:32 |

US3272169

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 2016' | (b) (4), (b) (6) | 15 Aug 2020 20:47:32 |

US3272169

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:47:32 |

US3272169

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:47:32 |

US3272169

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 2016' | (b) (4), (b) (6) | 15 Aug 2020 20:47:32 |

US3272169

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:47:32 |

US3272169

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2016' | System | 15 Aug 2020 20:47:32 |

US3272169

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2016' | System | 15 Aug 2020 20:47:32 |

US3272169

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2016' | System | 15 Aug 2020 20:47:32 |

US3272169

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2016' | System | 15 Aug 2020 20:47:32 |

US3272169

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:21:09

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Surgical and medical procedures, HLG: 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) | 25 Nov 2020 22:41:57 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:41:57 |
| Data point term sent to Coder | System | 25 Nov 2020 22:41:20 |
| User entered 'anterior fusion 3-7 pseudoarthrosis (c4-c7)' | (b) (4), (b) (6) | 25 Nov 2020 22:40:32 |
| DataPoint activated with code reason code Data required. | (b) (4), (b) (6) | 25 Nov 2020 22:38:30 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 15 Aug 2020 20:47:56 |

US3272169

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2016' | (b) (4), (b) (6) | 25 Nov 2020 22:40:32 |
| DataPoint activated with code reason code Data required. | | 25 Nov 2020 22:38:30 |
| DataPoint inactivated with code reason code Data not required. | | 15 Aug 2020 20:47:56 |

US3272169

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:40:32 |
| DataPoint activated with code reason code Data required. | | 25 Nov 2020 22:38:30 |
| DataPoint inactivated with code reason code Data not required. | | 15 Aug 2020 20:47:56 |

US3272169

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 22:40:32 |
| DataPoint activated with code reason code Data required. | | 25 Nov 2020 22:38:30 |
| DataPoint inactivated with code reason code Data not required. | | 15 Aug 2020 20:47:56 |

US3272169

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2016' | (b) (4), (b) (6) | 25 Nov 2020 22:40:32 |
| DataPoint activated with code reason code Data required. | | 25 Nov 2020 22:38:30 |
| DataPoint inactivated with code reason code Data not required. | | 15 Aug 2020 20:47:56 |

US3272169

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:40:32 |
| DataPoint activated with code reason code Data required. | | 25 Nov 2020 22:38:30 |
| DataPoint inactivated with code reason code Data not required. | | 15 Aug 2020 20:47:56 |

US3272169

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2016' | System | 25 Nov 2020 22:40:32 |
| DataPoint activated with code reason code Data required. | (b) (4), (b) (6) | 25 Nov 2020 22:38:30 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 15 Aug 2020 20:47:56 |

US3272169

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2016' | System | 25 Nov 2020 22:40:32 |
| DataPoint activated with code reason code Data required. | (b) (4), (b) (6) | 25 Nov 2020 22:38:30 |
| DataPoint inactivated with code reason code Data not required. | | 15 Aug 2020 20:47:56 |

US3272169

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2016' | System | 25 Nov 2020 22:40:32 |
| DataPoint activated with code reason code Data required. | (b) (4), (b) (6) | 25 Nov 2020 22:38:30 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 15 Aug 2020 20:47:56 |

US3272169

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2016' | System | 25 Nov 2020 22:40:32 |
| DataPoint activated with code reason code Data required. | (b) (4), (b) (6) | 25 Nov 2020 22:38:30 |
| DataPoint inactivated with code reason code Data not required. | | 15 Aug 2020 20:47:56 |

US3272169

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataract (left) - version MedDRA\\23.0. | Coder Import (b) (4) | 14 Oct 2020 17:27:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 14 Oct 2020 17:27:44 |
| Data point term sent to Coder | System | 14 Oct 2020 17:26:33 |
| User entered 'Cataract (Left eye)' | (b) (4), (b) (6) | 14 Oct 2020 17:25:33 |

US3272169

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2013' | (b) (4), (b) (6) | 14 Oct 2020 17:25:33 |

US3272169

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Oct 2020 17:25:33 |

US3272169

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Oct 2020 17:25:33 |

US3272169

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN May 2014' | (b) (4), (b) (6) | 14 Oct 2020 17:25:33 |

US3272169

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Oct 2020 17:25:33 |

US3272169

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2013' | System | 14 Oct 2020 17:25:33 |

US3272169

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2013' | System | 14 Oct 2020 17:25:33 |

US3272169

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'May 2014' | System | 14 Oct 2020 17:25:33 |

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Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2014' | System | 14 Oct 2020 17:25:33 |

US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Ocular disorders NEC, PT: Vitreous disorder, LLT: Disorder vitreous - version MedDRA\23.0. | Coder Import (b) (4) | 27 Nov 2020 21:28:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 27 Nov 2020 21:28:17 |
| Data point term sent to Coder | System | 25 Nov 2020 22:42:21 |
| User closed query 'CDM Coding: Thank you for the response. Please update the reported term as VITREOUS HUMOR (LEFT EYE)-DETAILS UNKNOWN to enable coding.' (Site from System). | System | 25 Nov 2020 22:41:33 |
| Query 'CDM Coding: Thank you for the response. Please update the reported term as VITREOUS HUMOR (LEFT EYE)-DETAILS UNKNOWN to enable coding.' answered with 'updated' (Site from System). | (b) (4), (b) (6) | 25 Nov 2020 22:41:33 |
| User entered 'VITREOUS HUMOR (LEFT EYE) (Details unknown)' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Nov 2020 22:41:25 |
| User opened query 'CDM Coding: Thank you for the response. Please update the reported term as VITREOUS HUMOR (LEFT EYE)-DETAILS UNKNOWN to enable coding.' (Site from System). | Coder Import (b) (4) | 24 Nov 2020 09:59:06 |
| Data point term sent to Coder | System | 23 Nov 2020 22:47:19 |
| User closed query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Vitreous degeneration Or Something else and amend /update the term accordingly in the diagnosis field to enable coding.' (Site from System). | System | 23 Nov 2020 22:47:08 |

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Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Vitreous degeneration Or Something else and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'subject does not know any other info on med history' (Site from System). | (b) (4), (b) (6) | 23 Nov 2020 22:47:08 |
| User opened query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Vitreous degeneration Or Something else and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System). | Coder Import (b) (4) | 23 Nov 2020 10:47:08 |
| Data point term sent to Coder | System | 20 Nov 2020 21:56:29 |
| User closed query 'Per CDM Coding: Please update the term with further information for a more specific meaning/diagnosis (symptom/condition). ' (Site from System). | System | 20 Nov 2020 21:56:13 |
| Query 'Per CDM Coding: Please update the term with further information for a more specific meaning/diagnosis (symptom/condition). ' answered with 'information listed is all patient knows as this condition has been resolved' (Site from System). | (b) (4), (b) (6) | 20 Nov 2020 21:56:13 |
| User opened query 'Per CDM Coding: Please update the term with further information for a more specific meaning/diagnosis (symptom/condition). ' (Site from System). | Coder Import (b) (4) | 16 Nov 2020 09:25:40 |
| Data point term sent to Coder | System | 20 Oct 2020 22:44:41 |
| User closed query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' (Site from System). | System | 20 Oct 2020 22:44:19 |
| Query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' answered with 'data is correct' (Site from System). | Kayla Flege (b) (4) | 20 Oct 2020 22:44:19 |
| User opened query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' (Site from System). | Coder Import (b) (4) | 15 Oct 2020 05:41:18 |
| Data point term sent to Coder | System | 14 Oct 2020 17:26:33 |

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Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:21:09

[Condition](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Vitreous humor (left eye)' | (b) (4), (b) (6) | 14 Oct 2020 17:26:17 |
| | | |

US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN May 2020' | (b) (4), (b) (6) | 14 Oct 2020 17:26:17 |

US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Oct 2020 17:26:17 |

US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Oct 2020 17:26:17 |

US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '8 Oct 2020' | (b) (4), (b) (6) | 14 Oct 2020 17:26:17 |

US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Oct 2020 17:26:17 |

US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'May 2020' | System | 14 Oct 2020 17:26:17 |

US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2020' | System | 14 Oct 2020 17:26:17 |

US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Oct 2020' | System | 14 Oct 2020 17:26:17 |

US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2020' | System | 14 Oct 2020 17:26:17 |

US3272169

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:44:57 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:44:57 |
| Data point term sent to Coder | System | 25 Nov 2020 22:44:23 |
| User entered 'cataract surgery (left eye)' | (b) (4), (b) (6) | 25 Nov 2020 22:44:17 |

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Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN May 2014' | (b) (4), (b) (6) | 25 Nov 2020 22:44:17 |

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Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:44:17 |

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Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 22:44:17 |

US3272169

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN May 2014' | (b) (4), (b) (6) | 25 Nov 2020 22:44:17 |

US3272169

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:44:17 |

US3272169

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'May 2014' | System | 25 Nov 2020 22:44:17 |

US3272169

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2014' | System | 25 Nov 2020 22:44:17 |

US3272169

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'May 2014' | System | 25 Nov 2020 22:44:17 |

US3272169

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2014' | System | 25 Nov 2020 22:44:17 |

US3272169

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM RQ : Response noted. as Celexa is being taken for both anxiety and depression. Please update CM# 1with both Indications (Depression and Anxiety) and review MH/CM date (s) else provide clarification' (Site from DM). | (b) (4), (b) (6) | 30 Dec 2020 11:38:57 |
| Query 'Per CDM RQ : Response noted. as Celexa is being taken for both anxiety and depression. Please update CM# 1with both Indications (Depression and Anxiety) and review MH/CM date (s) else provide clarification' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 28 Dec 2020 14:23:59 |
| User opened query 'Per CDM RQ : Response noted. as Celexa is being taken for both anxiety and depression. Please update CM# 1with both Indications (Depression and Anxiety) and review MH/CM date (s) else provide clarification' (Site from DM). | (b) (4), (b) (6) | 23 Dec 2020 14:43:29 |
| User closed query 'Per CDM RQ: Response noted 'celexa is being taken for both anixiety and depression'. Please update CM#1 indication to include 'ANXIETY' and review start MH/CM date(s) else clarify.' (Site from DM). | | 23 Dec 2020 14:43:29 |
| Query 'Per CDM RQ: Response noted 'celexa is being taken for both anixiety and depression'. Please update CM#1 indication to include 'ANXIETY' and review start MH/CM date(s) else clarify.' answered with 'That is how we had it, and got told to change it. What do you advise we do.' (Site from DM). | Kayla Flege (b) (4) | 14 Dec 2020 19:09:21 |
| User opened query 'Per CDM RQ: Response noted 'celexa is being taken for both anixiety and depression'. Please update CM#1 indication to include 'ANXIETY' and review start MH/CM date(s) else clarify.' (Site from DM). | (b) (4), (b) (6) | 14 Dec 2020 15:58:28 |

US3272169

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM). | (b) (4), (b) (6) | 14 Dec 2020 15:55:39 |
| Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' answered with 'celexa is being taken for both anxiety and depression' (Site from DM). | Kayla Flege (b) (4) | 09 Dec 2020 17:37:16 |
| User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM). | (b) (4), (b) (6) | 05 Dec 2020 12:16:11 |
| 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) | 25 Nov 2020 22:46:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:46:08 |
| Data point term sent to Coder | System | 25 Nov 2020 22:45:24 |
| User entered 'anxiety' | (b) (4), (b) (6) | 25 Nov 2020 22:44:37 |

US3272169

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2010' | (b) (4), (b) (6) | 25 Nov 2020 22:44:37 |

US3272169

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:44:37 |

US3272169

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 22:44:37 |

US3272169

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:44:37 |

US3272169

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:44:37 |

US3272169

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2010' | System | 25 Nov 2020 22:44:37 |

US3272169

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2010' | System | 25 Nov 2020 22:44:37 |

US3272169

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:44:37 |

US3272169

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:44:37 |

US3272169

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:21:09

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM RQ: Response noted ' there are medications she is taking for pain.' If CM is already recorded, please provide log line number ensuring indication matches with this condition else clarify.' (Site from DM). | (b) (4), (b) (6) | 23 Dec 2020 14:44:35 |
| Query 'Per CDM RQ: Response noted ' there are medications she is taking for pain.' If CM is already recorded, please provide log line number ensuring indication matches with this condition else clarify.' answered with 'Subject is not taking any medications for this condition.' (Site from DM). | Kayla Flege (b) (4) (b) (4) | 14 Dec 2020 19:09:46 |
| User opened query 'Per CDM RQ: Response noted ' there are medications she is taking for pain.' If CM is already recorded, please provide log line number ensuring indication matches with this condition else clarify.' (Site from DM). | (b) (4), (b) (6) | 14 Dec 2020 16:02:24 |
| User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM). | (b) (4), (b) (6) | 14 Dec 2020 16:01:15 |
| Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' answered with 'there are medications she is taking for pain.' (Site from DM). | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 17:37:43 |

US3272169

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:21:09

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM). | (b) (4), (b) (6) | 05 Dec 2020 12:16:21 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:46:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:46:08 |
| Data point term sent to Coder | System | 25 Nov 2020 22:45:24 |
| User entered 'abdominal pain' | (b) (4), (b) (6) | 25 Nov 2020 22:45:04 |

US3272169

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN May 2020' | (b) (4), (b) (6) | 25 Nov 2020 22:45:04 |

US3272169

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:45:04 |

US3272169

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 22:45:04 |
| | | |

US3272169

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:45:04 |

US3272169

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:45:04 |
| | | |

US3272169

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'May 2020' | System | 25 Nov 2020 22:45:04 |

US3272169

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2020' | System | 25 Nov 2020 22:45:04 |

US3272169

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:45:04 |

US3272169

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:45:04 |

US3272169

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM). | (b) (4), (b) (6) | 14 Dec 2020 16:03:13 |
| Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' answered with 'not taking any medications at this time.' (Site from DM). | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 17:38:12 |
| User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM). | (b) (4), (b) (6) | 05 Dec 2020 12:16:29 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 25 Nov 2020 22:48:06 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 25 Nov 2020 22:48:06 |
| Data point term sent to Coder | System | 25 Nov 2020 22:46:24 |
| User entered 'osteoporosis' | (b) (4), (b) (6) | 25 Nov 2020 22:45:46 |

US3272169

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2012' | (b) (4), (b) (6) | 25 Nov 2020 22:45:46 |

US3272169

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:45:46 |

US3272169

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 22:45:46 |

US3272169

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:45:46 |

US3272169

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:45:46 |

US3272169

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2012' | System | 25 Nov 2020 22:45:46 |

US3272169

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2012' | System | 25 Nov 2020 22:45:46 |

US3272169

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:45:46 |

US3272169

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:45:46 |

US3272169

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Substance abuse, LLT: Substance abuse - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:48:06 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:48:06 |
| Data point term sent to Coder | System | 25 Nov 2020 22:47:25 |
| User entered 'substance abuse' | (b) (4), (b) (6) | 25 Nov 2020 22:46:43 |

US3272169

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 1988' | (b) (4), (b) (6) | 25 Nov 2020 22:46:43 |

US3272169

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:46:43 |

US3272169

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 22:46:43 |

US3272169

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 06:29:29 |
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2012' | (b) (4), (b) (6) | 25 Nov 2020 22:46:43 |

US3272169

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:46:43 |

US3272169

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1988' | System | 25 Nov 2020 22:46:43 |

US3272169

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1988' | System | 25 Nov 2020 22:46:43 |

US3272169

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2012' | System | 25 Nov 2020 22:46:43 |

US3272169

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2012' | System | 25 Nov 2020 22:46:43 |

US3272169

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:49:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:49:38 |
| Data point term sent to Coder | System | 25 Nov 2020 22:48:28 |
| User entered 'post traumatic stress disorder' | (b) (4), (b) (6) | 25 Nov 2020 22:47:33 |

US3272169

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 1991' | (b) (4), (b) (6) | 25 Nov 2020 22:47:33 |

US3272169

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:47:33 |

US3272169

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 22:47:33 |

US3272169

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:47:33 |

US3272169

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:47:33 |

US3272169

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1991' | System | 25 Nov 2020 22:47:33 |

US3272169

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1991' | System | 25 Nov 2020 22:47:33 |

US3272169

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:47:33 |

US3272169

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:47:33 |

US3272169

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Psychiatric disorders, HLT: Personality disorders and disturbances in behaviour, HLT: Personality disorders with dramatic behaviour (Cluster B), PT: Borderline personality disorder, LLT: Borderline personality disorder - version MedDRA\\23.0. | Coder Import (b) (4) | 26 Nov 2020 04:41:10 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 26 Nov 2020 04:41:10 |
| Data point term sent to Coder | System | 25 Nov 2020 22:48:28 |
| User entered 'border line personality disorder' | (b) (4), (b) (6) | 25 Nov 2020 22:48:05 |

US3272169

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2010' | (b) (4), (b) (6) | 25 Nov 2020 22:48:05 |

US3272169

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:48:05 |

US3272169

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 22:48:05 |

US3272169

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:48:05 |

US3272169

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:48:05 |

US3272169

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2010' | System | 25 Nov 2020 22:48:05 |

US3272169

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2010' | System | 25 Nov 2020 22:48:05 |

US3272169

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:48:05 |

US3272169

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:48:05 |

US3272169

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM). | (b) (4), (b) (6) | 14 Jan 2021 10:11:41 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'per patient no meds taken' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 18:02:45 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM). | (b) (4), (b) (6) | 09 Jan 2021 21:10:48 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:50:02 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:50:02 |
| Data point term sent to Coder | System | 25 Nov 2020 22:49:29 |
| User entered 'bipolar disorder' | (b) (4), (b) (6) | 25 Nov 2020 22:48:30 |

US3272169

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2019' | (b) (4), (b) (6) | 25 Nov 2020 22:48:30 |

US3272169

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 06:29:29 |
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:48:30 |

US3272169

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 22:48:30 |

US3272169

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:48:30 |

US3272169

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:48:30 |

US3272169

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2019' | System | 25 Nov 2020 22:48:30 |

US3272169

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2019' | System | 25 Nov 2020 22:48:30 |

US3272169

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:48:30 |

US3272169

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:48:30 |

US3272169

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:50:00 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:50:00 |
| Data point term sent to Coder | System | 25 Nov 2020 22:49:29 |
| User entered 'mild asthma' | (b) (4), (b) (6) | 25 Nov 2020 22:48:51 |

US3272169

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 1978' | (b) (4), (b) (6) | 25 Nov 2020 22:48:51 |

US3272169

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:48:51 |

US3272169

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 22:48:51 |

US3272169

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:48:51 |

US3272169

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 06:29:29 |
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:48:51 |

US3272169

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1978' | System | 25 Nov 2020 22:48:51 |

US3272169

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1978' | System | 25 Nov 2020 22:48:51 |

US3272169

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:48:51 |

US3272169

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:48:51 |

US3272169

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:21:09

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM). | (b) (4), (b) (6) | 14 Dec 2020 16:03:31 |
| Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' answered with 'not taking any medications for this at this time.' (Site from DM). | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 17:39:13 |
| User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM). | (b) (4), (b) (6) | 05 Dec 2020 12:16:58 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 25 Nov 2020 22:51:12 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 25 Nov 2020 22:51:12 |
| Data point term sent to Coder | System | 25 Nov 2020 22:50:29 |
| User entered 'chronic obstructive pulmonary disease' | (b) (4), (b) (6) | 25 Nov 2020 22:49:30 |

US3272169

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2013' | (b) (4), (b) (6) | 25 Nov 2020 22:49:30 |

US3272169

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:49:30 |

US3272169

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 22:49:30 |

US3272169

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:49:30 |

US3272169

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:49:30 |

US3272169

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2013' | System | 25 Nov 2020 22:49:30 |

US3272169

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2013' | System | 25 Nov 2020 22:49:30 |

US3272169

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:49:30 |

US3272169

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:49:30 |

US3272169

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM). | (b) (4), (b) (6) | 14 Dec 2020 16:03:44 |
| Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' answered with 'not taking any medications at this time.' (Site from DM). | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 17:39:43 |
| User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM). | (b) (4), (b) (6) | 05 Dec 2020 12:17:14 |
| User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 25 Nov 2020 22:51:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 25 Nov 2020 22:51:16 |
| Data point term sent to Coder | System | 25 Nov 2020 22:50:29 |
| User entered 'hypotension' | (b) (4), (b) (6) | 25 Nov 2020 22:49:47 |

US3272169

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2013' | (b) (4), (b) (6) | 25 Nov 2020 22:49:47 |

US3272169

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:49:47 |

US3272169

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 22:49:47 |

US3272169

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:49:47 |

US3272169

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:49:47 |

US3272169

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2013' | System | 25 Nov 2020 22:49:47 |

US3272169

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2013' | System | 25 Nov 2020 22:49:47 |

US3272169

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:49:47 |

US3272169

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:49:47 |

US3272169

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve prolapse, LLT: Mitral valve prolapse - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:51:12 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:51:12 |
| Data point term sent to Coder | System | 25 Nov 2020 22:50:29 |
| User entered 'mitral valve prolapse' | (b) (4), (b) (6) | 25 Nov 2020 22:50:13 |

US3272169

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2013' | (b) (4), (b) (6) | 25 Nov 2020 22:50:13 |

US3272169

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:50:13 |

US3272169

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 22:50:13 |

US3272169

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:50:13 |

US3272169

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:50:13 |

US3272169

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2013' | System | 25 Nov 2020 22:50:13 |

US3272169

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2013' | System | 25 Nov 2020 22:50:13 |

US3272169

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:50:13 |

US3272169

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:50:13 |

US3272169

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Supraventricular tachycardia, LLT: Supraventricular tachycardia - version MedDRA\\23.0. | Coder Import (b) (4) | 26 Nov 2020 06:09:02 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 26 Nov 2020 06:09:02 |
| Data point term sent to Coder | System | 25 Nov 2020 22:51:30 |
| User entered 'supra ventricular tachycardia (svt)' | (b) (4), (b) (6) | 25 Nov 2020 22:51:18 |

US3272169

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2013' | (b) (4), (b) (6) | 25 Nov 2020 22:51:18 |

US3272169

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:51:18 |

US3272169

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 22:51:18 |

US3272169

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:51:18 |

US3272169

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:51:18 |

US3272169

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2013' | System | 25 Nov 2020 22:51:18 |

US3272169

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2013' | System | 25 Nov 2020 22:51:18 |

US3272169

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:51:18 |

US3272169

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered empty. | System | 25 Nov 2020 22:51:18 |

US3272169

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:54:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:54:04 |
| Data point term sent to Coder | System | 25 Nov 2020 22:52:30 |
| User entered 'syncope' | (b) (4), (b) (6) | 25 Nov 2020 22:52:14 |

US3272169

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '16 Jul 2017' | (b) (4), (b) (6) | 25 Nov 2020 22:52:14 |

US3272169

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:52:14 |

US3272169

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 22:52:14 |

US3272169

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '16 Jul 2017' | (b) (4), (b) (6) | 25 Nov 2020 22:52:14 |

US3272169

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:52:14 |

US3272169

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jul 2017' | System | 25 Nov 2020 22:52:14 |

US3272169

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2017' | System | 25 Nov 2020 22:52:14 |

US3272169

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jul 2017' | System | 25 Nov 2020 22:52:14 |

US3272169

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2017' | System | 25 Nov 2020 22:52:14 |

US3272169

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:54:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:54:04 |
| Data point term sent to Coder | System | 25 Nov 2020 22:53:31 |
| User entered 'tonsillitis' | (b) (4), (b) (6) | 25 Nov 2020 22:52:48 |

US3272169

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 1975' | (b) (4), (b) (6) | 25 Nov 2020 22:52:48 |

US3272169

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:52:48 |
| | | |

US3272169

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 22:52:48 |

US3272169

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 1975' | (b) (4), (b) (6) | 25 Nov 2020 22:52:48 |

US3272169

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:52:48 |

US3272169

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1975' | System | 25 Nov 2020 22:52:48 |

US3272169

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1975' | System | 25 Nov 2020 22:52:48 |

US3272169

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1975' | System | 25 Nov 2020 22:52:48 |

US3272169

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1975' | System | 25 Nov 2020 22:52:48 |

US3272169

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Adenoiditis, LLT: Adenoiditis - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:54:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 22:54:04 |
| Data point term sent to Coder | System | 25 Nov 2020 22:53:31 |
| User entered 'adenoiditis' | (b) (4), (b) (6) | 25 Nov 2020 22:53:31 |

US3272169

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 1975' | (b) (4), (b) (6) | 25 Nov 2020 22:53:31 |

US3272169

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:53:31 |

US3272169

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 22:53:31 |

US3272169

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 1975' | (b) (4), (b) (6) | 25 Nov 2020 22:53:31 |

US3272169

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:53:31 |

US3272169

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1975' | System | 25 Nov 2020 22:53:31 |

US3272169

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1975' | System | 25 Nov 2020 22:53:31 |

US3272169

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:21:09

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1975' | System | 25 Nov 2020 22:53:31 |

US3272169

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:21:09

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1975' | System | 25 Nov 2020 22:53:31 |

US3272169

Folder: Screening

Form: Medical History (36)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac therapeutic procedures NEC, PT: Cardiac ablation, LLT: Cardiac ablation - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 23:44:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 23:44:04 |
| Data point term sent to Coder | System | 25 Nov 2020 23:43:09 |
| User entered 'cardiac ablation' | (b) (4), (b) (6) | 25 Nov 2020 23:42:23 |

US3272169

Folder: Screening

Form: Medical History (36)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 25 Nov 2020 23:42:23 |

US3272169

Folder: Screening

Form: Medical History (36)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:42:23 |

US3272169

Folder: Screening

Form: Medical History (36)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:42:23 |

US3272169

Folder: Screening

Form: Medical History (36)

Generated On: 09 Jun 2021 16:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 25 Nov 2020 23:42:23 |

US3272169

Folder: Screening

Form: Medical History (36)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:42:23 |

US3272169

Folder: Screening

Form: Medical History (36)

Generated On: 09 Jun 2021 16:21:09

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2018' | System | 25 Nov 2020 23:42:23 |

US3272169

Folder: Screening

Form: Medical History (36)

Generated On: 09 Jun 2021 16:21:09

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2018' | System | 25 Nov 2020 23:42:23 |

US3272169

Folder: Screening

Form: Medical History (36)

Generated On: 09 Jun 2021 16:21:09

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2018' | System | 25 Nov 2020 23:42:23 |

US3272169

Folder: Screening

Form: Medical History (36)

Generated On: 09 Jun 2021 16:21:09

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 06:29:29 |
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered '2018' | System | 25 Nov 2020 23:42:23 |

US3272169

Folder: Screening

Form: Medical History (37)

Generated On: 09 Jun 2021 16:21:09

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac imaging procedures, PT: Catheterisation cardiac, LLT: Cardiac catheterization - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 23:44:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 23:44:04 |
| Data point term sent to Coder | System | 25 Nov 2020 23:43:09 |
| User entered 'heart cath' | (b) (4), (b) (6) | 25 Nov 2020 23:42:56 |

US3272169

Folder: Screening

Form: Medical History (37)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2013' | (b) (4), (b) (6) | 25 Nov 2020 23:42:56 |

US3272169

Folder: Screening

Form: Medical History (37)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:42:56 |

US3272169

Folder: Screening

Form: Medical History (37)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:42:56 |

US3272169

Folder: Screening

Form: Medical History (37)

Generated On: 09 Jun 2021 16:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2013' | (b) (4), (b) (6) | 25 Nov 2020 23:42:56 |

US3272169

Folder: Screening

Form: Medical History (37)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:42:56 |

US3272169

Folder: Screening

Form: Medical History (37)

Generated On: 09 Jun 2021 16:21:09

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2013' | System | 25 Nov 2020 23:42:56 |

US3272169

Folder: Screening

Form: Medical History (37)

Generated On: 09 Jun 2021 16:21:09

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2013' | System | 25 Nov 2020 23:42:56 |

US3272169

Folder: Screening

Form: Medical History (37)

Generated On: 09 Jun 2021 16:21:09

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2013' | System | 25 Nov 2020 23:42:56 |

US3272169

Folder: Screening

Form: Medical History (37)

Generated On: 09 Jun 2021 16:21:09

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2013' | System | 25 Nov 2020 23:42:56 |

US3272169

Folder: Screening

Form: Medical History (38)

Generated On: 09 Jun 2021 16:21:09

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Adenotonsillectomy, LLT: Tonsillectomy & Adenoidectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 23:45:59 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 23:45:59 |
| Data point term sent to Coder | System | 25 Nov 2020 23:45:10 |
| User entered 'tonsillectomy/adenoidectomy' | (b) (4), (b) (6) | 25 Nov 2020 23:44:37 |

US3272169

Folder: Screening

Form: Medical History (38)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 1975' | (b) (4), (b) (6) | 25 Nov 2020 23:44:37 |

US3272169

Folder: Screening

Form: Medical History (38)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:44:37 |

US3272169

Folder: Screening

Form: Medical History (38)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:44:37 |

US3272169

Folder: Screening

Form: Medical History (38)

Generated On: 09 Jun 2021 16:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 1975' | (b) (4), (b) (6) | 25 Nov 2020 23:44:37 |

US3272169

Folder: Screening

Form: Medical History (38)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:44:37 |

US3272169

Folder: Screening

Form: Medical History (38)

Generated On: 09 Jun 2021 16:21:09

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1975' | System | 25 Nov 2020 23:44:37 |

US3272169

Folder: Screening

Form: Medical History (38)

Generated On: 09 Jun 2021 16:21:09

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1975' | System | 25 Nov 2020 23:44:37 |

US3272169

Folder: Screening

Form: Medical History (38)

Generated On: 09 Jun 2021 16:21:09

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1975' | System | 25 Nov 2020 23:44:37 |

US3272169

Folder: Screening

Form: Medical History (38)

Generated On: 09 Jun 2021 16:21:09

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1975' | System | 25 Nov 2020 23:44:37 |

US3272169

Folder: Screening

Form: Medical History (39)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Gun shot wound, LLT: Gun shot wound - version MedDRA\\23.0. | Coder Import (b) (4) | 26 Nov 2020 06:13:07 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 26 Nov 2020 06:13:07 |
| Data point term sent to Coder | System | 25 Nov 2020 23:46:18 |
| User entered 'trauma surgery (post gun shot wound left armpit)' | (b) (4), (b) (6) | 25 Nov 2020 23:45:57 |

US3272169

Folder: Screening

Form: Medical History (39)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 1991' | (b) (4), (b) (6) | 25 Nov 2020 23:45:57 |

US3272169

Folder: Screening

Form: Medical History (39)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:45:57 |

US3272169

Folder: Screening

Form: Medical History (39)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:45:57 |

US3272169

Folder: Screening

Form: Medical History (39)

Generated On: 09 Jun 2021 16:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 1991' | (b) (4), (b) (6) | 25 Nov 2020 23:45:57 |

US3272169

Folder: Screening

Form: Medical History (39)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:45:57 |

US3272169

Folder: Screening

Form: Medical History (39)

Generated On: 09 Jun 2021 16:21:09

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1991' | System | 25 Nov 2020 23:45:57 |

US3272169

Folder: Screening

Form: Medical History (39)

Generated On: 09 Jun 2021 16:21:09

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1991' | System | 25 Nov 2020 23:45:57 |

US3272169

Folder: Screening

Form: Medical History (39)

Generated On: 09 Jun 2021 16:21:09

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 1991' | System | 25 Nov 2020 23:45:57 |

US3272169

Folder: Screening

Form: Medical History (39)

Generated On: 09 Jun 2021 16:21:09

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '1991' | System | 25 Nov 2020 23:45:57 |

US3272169

Folder: Screening

Form: Medical History (40)

Generated On: 09 Jun 2021 16:21:09

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac imaging procedures, PT: Catheterisation cardiac, LLT: Cardiac catheterization - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 23:48:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 23:48:04 |
| Data point term sent to Coder | System | 25 Nov 2020 23:47:19 |
| User entered 'heart cath' | (b) (4), (b) (6) | 25 Nov 2020 23:46:19 |

US3272169

Folder: Screening

Form: Medical History (40)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 25 Nov 2020 23:46:19 |

US3272169

Folder: Screening

Form: Medical History (40)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:46:19 |

US3272169

Folder: Screening

Form: Medical History (40)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:46:19 |

US3272169

Folder: Screening

Form: Medical History (40)

Generated On: 09 Jun 2021 16:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 25 Nov 2020 23:46:19 |

US3272169

Folder: Screening

Form: Medical History (40)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:46:19 |

US3272169

Folder: Screening

Form: Medical History (40)

Generated On: 09 Jun 2021 16:21:09

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2018' | System | 25 Nov 2020 23:46:19 |

US3272169

Folder: Screening

Form: Medical History (40)

Generated On: 09 Jun 2021 16:21:09

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2018' | System | 25 Nov 2020 23:46:19 |

US3272169

Folder: Screening

Form: Medical History (40)

Generated On: 09 Jun 2021 16:21:09

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2018' | System | 25 Nov 2020 23:46:19 |

US3272169

Folder: Screening

Form: Medical History (40)

Generated On: 09 Jun 2021 16:21:09

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2018' | System | 25 Nov 2020 23:46:19 |

US3272169

Folder: Screening

Form: Medical History (41)

Generated On: 09 Jun 2021 16:21:09

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Apr 2021 09:24:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Apr 2021 09:24:42 |
| Data point term sent to Coder | System | 14 Apr 2021 20:02:40 |
| User entered 'Botox injection, facial' | Whitney West (b) (4) | 14 Apr 2021 20:02:37 |

US3272169

Folder: Screening

Form: Medical History (41)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered 'un UNK 2018' | Whitney West (b) (4) (b) (4) | 14 Apr 2021 20:02:37 |

US3272169

Folder: Screening

Form: Medical History (41)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered '0' | Whitney West (b) (4) (b) (4) | 14 Apr 2021 20:02:37 |

US3272169

Folder: Screening

Form: Medical History (41)

Generated On: 09 Jun 2021 16:21:09

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered 'No (N)' | Whitney West (b) (4) (b) (4) | 14 Apr 2021 20:02:37 |

US3272169

Folder: Screening

Form: Medical History (41)

Generated On: 09 Jun 2021 16:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered 'un UNK 2018' | Whitney West (b) (4) (b) (4) | 14 Apr 2021 20:02:37 |

US3272169

Folder: Screening

Form: Medical History (41)

Generated On: 09 Jun 2021 16:21:09

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered '0' | Whitney West (b) (4) (b) (4) | 14 Apr 2021 20:02:37 |

US3272169

Folder: Screening

Form: Medical History (41)

Generated On: 09 Jun 2021 16:21:09

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2018' | System | 14 Apr 2021 20:02:37 |

US3272169

Folder: Screening

Form: Medical History (41)

Generated On: 09 Jun 2021 16:21:09

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2018' | System | 14 Apr 2021 20:02:37 |

US3272169

Folder: Screening

Form: Medical History (41)

Generated On: 09 Jun 2021 16:21:09

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered 'Jan 2018' | System | 14 Apr 2021 20:02:37 |

US3272169

Folder: Screening

Form: Medical History (41)

Generated On: 09 Jun 2021 16:21:09

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:59:04 |
| Data hard unlocked. | | 30 Apr 2021 06:29:29 |
| Data hard locked. | | 28 Apr 2021 20:50:18 |
| User entered '2018' | System | 14 Apr 2021 20:02:37 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM). | (b) (4), (b) (6) | 30 Sep 2020 08:23:49 |
| Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'updated' (Site from DM). | Ashley Bell (b) (4) | 25 Sep 2020 22:19:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Ashley Bell (b) (4) | 25 Sep 2020 22:19:01 |
| User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM). | (b) (4), (b) (6) | 25 Sep 2020 13:09:17 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:12:48 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '15 Aug 2020' reason for change: Data Entry Error | Ashley Bell (b) (4) | 25 Sep 2020 22:19:01 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:12:48 |
| User entered '15 Aug 2020' | | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '13:55' reason for change: Data Entry Error | Ashley Bell (b) (4) | 25 Sep 2020 22:19:01 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:12:48 |
| User entered '13:55' | | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered '15 Aug 2020 13:55' | System | 25 Sep 2020 22:19:01 |
| User entered empty. | System | 16 Sep 2020 16:12:48 |
| User entered '15 Aug 2020 13:55' | System | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '173.5' cm reason for change: Data Entry Error | Ashley Bell (b) (4) | 25 Sep 2020 22:19:01 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:12:48 |
| User entered '173.5' cm | | 15 Aug 2020 20:40:40 |
| DataPoint set to visible. | System | 15 Aug 2020 20:07:17 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Weight \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '59.7' kg reason for change: Data Entry Error | Ashley Bell (b) (4) | 25 Sep 2020 22:19:01 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:12:48 |
| User entered '59.7' kg | | 15 Aug 2020 20:40:40 |
| DataPoint set to visible. | System | 15 Aug 2020 20:07:17 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered '19.83240' | System | 25 Sep 2020 22:19:01 |
| User entered empty. | System | 16 Sep 2020 16:12:48 |
| User entered '19.8' | System | 15 Aug 2020 20:40:40 |
| DataPoint set to visible. | System | 15 Aug 2020 20:07:17 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered 'kg/m2' | System | 25 Sep 2020 22:19:01 |
| User entered empty. | System | 16 Sep 2020 16:12:48 |
| User entered 'kg/m2' | System | 15 Aug 2020 20:40:40 |
| DataPoint set to visible. | System | 15 Aug 2020 20:07:17 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM). | (b) (4), (b) (6) | 30 Sep 2020 08:23:51 |
| Query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' answered with 'updated' (Site from DM). | Ashley Bell (b) (4) | 25 Sep 2020 22:19:16 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Ashley Bell (b) (4) | 25 Sep 2020 22:19:01 |
| User opened query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM). | (b) (4), (b) (6) | 25 Sep 2020 13:09:20 |
| User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM). | (b) (4), (b) (6) | 25 Sep 2020 13:09:20 |
| Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 16 Sep 2020 16:12:53 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:12:48 |
| User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 21:15:44 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered '37' C | (b) (4), (b) (6) | 15 Aug 2020 20:40:40 |
| | | |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:12:48 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Ashley Bell (b) (4) | 25 Sep 2020 22:19:01 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:12:48 |
| User entered '69' | | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered 'bpm' | System | 25 Sep 2020 22:19:01 |
| User entered empty. | System | 16 Sep 2020 16:12:48 |
| User entered 'bpm' | System | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Ashley Bell (b) (4) | 25 Sep 2020 22:19:01 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:12:48 |
| User entered '16' | | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered 'breaths/min' | System | 25 Sep 2020 22:19:01 |
| User entered empty. | System | 16 Sep 2020 16:12:48 |
| User entered 'breaths/min' | System | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Ashley Bell (b) (4) | 25 Sep 2020 22:19:01 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:12:48 |
| User entered '119' | | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered 'mmHg' | System | 25 Sep 2020 22:19:01 |
| User entered empty. | System | 16 Sep 2020 16:12:48 |
| User entered 'mmHg' | System | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Ashley Bell (b) (4) | 25 Sep 2020 22:19:01 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:12:48 |
| User entered '87' | | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User entered 'mmHg' | System | 25 Sep 2020 22:19:01 |
| User entered empty. | System | 16 Sep 2020 16:12:48 |
| User entered 'mmHg' | System | 15 Aug 2020 20:40:40 |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| | | |

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| | | |

US3272169

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:09

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Dec 2020 15:54:56 |
| User entered 'No (N)' reason for change: Data Entry Error | | 16 Sep 2020 18:28:47 |
| User entered 'Yes (Y)' | | 15 Aug 2020 20:40:06 |

US3272169

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:09

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System). | System | 28 Dec 2020 15:55:04 |
| Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System). | System | 28 Dec 2020 15:55:04 |
| User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System | 28 Dec 2020 15:55:04 |
| User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System). | System | 28 Dec 2020 15:55:04 |
| User entered '15 Aug 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Dec 2020 15:55:04 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System | 28 Dec 2020 15:54:56 |
| User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System). | System | 28 Dec 2020 15:54:56 |
| User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System). | System | 28 Dec 2020 15:54:56 |
| User entered '15 Apr 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Dec 2020 15:54:56 |
| User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System | 16 Sep 2020 18:28:47 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 18:28:47 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System | 16 Sep 2020 17:49:58 |
| User entered '15 Aug 2020' | (b) (4), (b) (6) | 15 Aug 2020 20:40:06 |

US3272169

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:21:09

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '15 Aug 2020' | (b) (4), (b) (6) | 15 Aug 2020 20:39:55 |

US3272169

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:21:09

[Is the participant of childbearing potential?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:39:55 |

US3272169

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:21:09

[If No, what is the reason?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Surgically sterile (SURGICALLY STERILE)' | (b) (4), (b) (6) | 15 Aug 2020 20:39:55 |

US3272169

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:21:09

[If Partner medically sterile or Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:39:55 |

US3272169

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:21:09

If Surgically sterile, date of surgery (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'un UNK 1999' | (b) (4), (b) (6) | 15 Aug 2020 20:39:55 |

US3272169

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:21:09

[Date of surgery unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:39:55 |

US3272169

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:21:09

If Post-menopausal, date of last menstruation (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:39:55 |

US3272169

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:21:09

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:39:55 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Other

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Resides in a single family home (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

Other

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:09

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:50:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:38:59 |

US3272169

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:57:44 |

US3272169

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '15 Aug 2020' | (b) (4), (b) (6) | 15 Aug 2020 20:57:44 |

US3272169

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 15 Aug 2020 20:57:44 |

US3272169

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered 'VISIT1' | System | 15 Aug 2020 20:57:44 |

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:09

What was the date of randomization? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '15 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Aug 2020 19:29:20 |

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:09

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Aug 2020 04:52:24 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 04:52:24 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 15 Aug 2020 19:29:20 |
| User entered '104796' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Aug 2020 19:29:20 |

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:09

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Aug 2020 19:29:20 |

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:09

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:58:02 |

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:09

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:58:02 |

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:09

Severe obesity (body mass index > or = 40kg/m2)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:58:02 |

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:09

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:58:02 |

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:09

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:58:02 |

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:09

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Dec 2020 15:55:38 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:22:10 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 07:31:55 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:09

Height

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:19:59 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Sep 2020 16:04:51 |
| Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM). | Ashley Bell (b) (4) | 04 Sep 2020 00:22:50 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Ashley Bell (b) (4) | 04 Sep 2020 00:22:45 |
| User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM). | (b) (4), (b) (6) | 28 Aug 2020 18:48:57 |
| User entered '173.5' cm | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:09

Weight

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Sep 2020 16:04:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Ashley Bell (b) (4) | 04 Sep 2020 00:22:45 |
| User entered '59.7' kg | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:09

Height

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:19:59 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Sep 2020 16:04:51 |
| Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM). | Ashley Bell (b) (4) | 04 Sep 2020 00:22:50 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Ashley Bell (b) (4) | 04 Sep 2020 00:22:45 |
| User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM). | (b) (4), (b) (6) | 28 Aug 2020 18:48:57 |
| User entered '173.5' cm | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:09

Weight

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Sep 2020 16:04:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Ashley Bell (b) (4) | 04 Sep 2020 00:22:45 |
| User entered '59.7' kg | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User accepted default value 'Pre-Dose (PREDOSE)' | | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '15 Aug 2020' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '13:55' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered '15 Aug 2020 13:55' | System | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '37' C | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '69' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered 'bpm' | System | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '16' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered 'breaths/min' | System | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '119' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered 'mmHg' | System | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '87' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered 'mmHg' | System | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:09

Height

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:19:59 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Sep 2020 16:04:51 |
| Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM). | Ashley Bell (b) (4) | 04 Sep 2020 00:22:50 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Ashley Bell (b) (4) | 04 Sep 2020 00:22:45 |
| User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM). | (b) (4), (b) (6) | 28 Aug 2020 18:48:57 |
| User entered '173.5' cm | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:09

Weight

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Sep 2020 16:04:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Ashley Bell (b) (4) | 04 Sep 2020 00:22:45 |
| User entered '59.7' kg | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User accepted default value 'Post-Dose (POSTDOSE)' | | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '15 Aug 2020' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 18 Aug 2020 22:07:15 |
| User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | | 15 Aug 2020 20:59:43 |
| User entered '15:22' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered '15 Aug 2020 15:22' | System | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 11 Sep 2020 21:24:16 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 11 Sep 2020 21:24:16 |
| User entered '36.5' C reason for change: Data Entry Error | (b) (4), (b) (6) | 11 Sep 2020 21:24:16 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 15 Aug 2020 20:59:43 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 11 Sep 2020 21:24:16 |
| User entered 'Other (Other)' reason for change: Data Entry Error | (b) (4), (b) (6) | 11 Sep 2020 21:24:16 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 15 Aug 2020 20:59:43 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'temporal' reason for change: Data Entry Error | (b) (4), (b) (6) | 11 Sep 2020 21:24:16 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '64' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered 'bpm' | System | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '16' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered 'breaths/min' | System | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '111' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered 'mmHg' | System | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '80' | (b) (4), (b) (6) | 15 Aug 2020 20:59:43 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered 'mmHg' | System | 15 Aug 2020 20:59:43 |

US3272169

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:09

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:59:55 |

US3272169

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:09

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '15 Aug 2020' | (b) (4), (b) (6) | 15 Aug 2020 20:59:55 |

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | Kayla Flege (b) (4) | 15 Aug 2020 20:07:42 |

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Kayla Flege (b) (4) | 15 Aug 2020 20:07:42 |

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Kayla Flege (b) (4) | 15 Aug 2020 20:07:42 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '15 Aug 2020' | Kayla Flege (b) (4) | 15 Aug 2020 20:07:42 |

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '14:52' | Kayla Flege (b) (4) | 15 Aug 2020 20:07:42 |

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered '15 Aug 2020 14:52' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Left Arm (LEFT ARM)' | Kayla Flege (b) (4) | 15 Aug 2020 20:07:42 |

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered 'ONCE' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered 'INTRAMUSCULAR' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 21:00:22 |

US3272169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '15 Aug 2020' | (b) (4), (b) (6) | 15 Aug 2020 21:00:22 |

US3272169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '14:15' | (b) (4), (b) (6) | 15 Aug 2020 21:00:22 |

US3272169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered '15 Aug 2020 14:15' | System | 15 Aug 2020 21:00:22 |

US3272169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:21:09

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '15 Aug 2020' | (b) (4), (b) (6) | 15 Aug 2020 21:00:43 |

US3272169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:09

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | | 15 Aug 2020 21:00:43 |

US3272169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:09

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 21:00:43 |

US3272169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:09

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '14:04' | (b) (4), (b) (6) | 15 Aug 2020 21:00:43 |

US3272169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:09

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered '15 Aug 2020 14:04' | System | 15 Aug 2020 21:00:43 |

US3272169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:09

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 15 Aug 2020 21:00:43 |

US3272169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:09

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 21:00:43 |

US3272169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:09

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 21:00:43 |

US3272169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:09

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered empty. | System | 15 Aug 2020 21:00:43 |

US3272169

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 15 Aug 2020 21:01:05 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 15 Aug 2020 21:01:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Aug 2020 21:01:05 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 15 Aug 2020 21:00:52 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 21:00:52 |

US3272169

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:46 |
| User entered '1' | System | 15 Aug 2020 21:01:05 |
| User entered empty. | System | 15 Aug 2020 21:00:52 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:15:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '32185203-914c-4fad-bfc7-dc6bc2d0f2cc' | System | 15 Aug 2020 20:16:16 |
| User entered 'Yes (Y)' | System | 15 Aug 2020 20:16:16 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:15:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '32185203-914c-4fad-bfc7-dc6bc2d0f2cc' | System | 15 Aug 2020 20:16:16 |
| User entered '98.4' | System | 15 Aug 2020 20:16:16 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:16:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '32185203-914c-4fad-bfc7-dc6bc2d0f2cc' | System | 15 Aug 2020 20:16:16 |
| User entered 'No (N)' | System | 15 Aug 2020 20:16:16 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:16:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '32185203-914c-4fad-bfc7-dc6bc2d0f2cc' | System | 15 Aug 2020 20:16:16 |
| User entered '15 Aug 2020 15:16' | System | 15 Aug 2020 20:16:16 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '15 Aug 2020 15:12' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '15 Aug 2020 17:42' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 1, after vaccination (at home)' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:03:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '84b185da-b754-4989-93c6-a12726b08092' | System | 16 Aug 2020 02:03:45 |
| User entered 'Yes (Y)' | System | 16 Aug 2020 02:03:45 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:03:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '84b185da-b754-4989-93c6-a12726b08092' | System | 16 Aug 2020 02:03:45 |
| User entered '98.7' | System | 16 Aug 2020 02:03:45 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:03:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '84b185da-b754-4989-93c6-a12726b08092' | System | 16 Aug 2020 02:03:45 |
| User entered 'No (N)' | System | 16 Aug 2020 02:03:45 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:03:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '84b185da-b754-4989-93c6-a12726b08092' | System | 16 Aug 2020 02:03:45 |
| User entered '15 Aug 2020 21:03' | System | 16 Aug 2020 02:03:45 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '15 Aug 2020 18:37' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 2' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:55:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c9c10b2-aca9-4bea-8f24-f2d634da95f9' | System | 16 Aug 2020 20:56:14 |
| User entered 'No (N)' | System | 16 Aug 2020 20:56:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:55:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c9c10b2-aca9-4bea-8f24-f2d634da95f9' | System | 16 Aug 2020 20:56:14 |
| User entered 'Yes (Y)' | System | 16 Aug 2020 20:56:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated con med log' (Site from System). | | 16 Sep 2020 13:38:02 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c9c10b2-aca9-4bea-8f24-f2d634da95f9' | System | 16 Aug 2020 20:56:14 |
| User entered '1' | System | 16 Aug 2020 20:56:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c9c10b2-aca9-4bea-8f24-f2d634da95f9' User entered '0' | System | 16 Aug 2020 20:56:14 |
| | System | 16 Aug 2020 20:56:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c9c10b2-aca9-4bea-8f24-f2d634da95f9' | System | 16 Aug 2020 20:56:14 |
| User entered '16 Aug 2020 15:56' | System | 16 Aug 2020 20:56:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '17 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 3' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:49:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd505c133-07ff-406f-aaad-8e63dd83ae06' | System | 18 Aug 2020 02:50:15 |
| User entered 'Yes (Y)' | System | 18 Aug 2020 02:50:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:49:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd505c133-07ff-406f-aaad-8e63dd83ae06' | System | 18 Aug 2020 02:50:15 |
| User entered '98.6' | System | 18 Aug 2020 02:50:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd505c133-07ff-406f-aaad-8e63dd83ae06' | System | 18 Aug 2020 02:50:15 |
| User entered 'Yes (Y)' | System | 18 Aug 2020 02:50:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated con med log' (Site from System). | (b) (4), (b) (6) | 16 Sep 2020 13:38:12 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 11 Sep 2020 22:51:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd505c133-07ff-406f-aaad-8e63dd83ae06' | System | 18 Aug 2020 02:50:15 |
| User entered '1' | System | 18 Aug 2020 02:50:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd505c133-07ff-406f-aaad-8e63dd83ae06' | System | 18 Aug 2020 02:50:15 |
| User entered '0' | System | 18 Aug 2020 02:50:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd505c133-07ff-406f-aaad-8e63dd83ae06' | System | 18 Aug 2020 02:50:15 |
| User entered '17 Aug 2020 21:50' | System | 18 Aug 2020 02:50:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '17 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '18 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 4' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:41:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '67d08138-2bcd-4da2-af87-2f8dd1d0e902' | System | 19 Aug 2020 04:41:59 |
| User entered 'Yes (Y)' | System | 19 Aug 2020 04:41:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:41:47', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '67d08138-2bcd-4da2-af87-2f8dd1d0e902' | System | 19 Aug 2020 04:41:59 |
| User entered '97.0' | System | 19 Aug 2020 04:41:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:41:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '67d08138-2bcd-4da2-af87-2f8dd1d0e902' | System | 19 Aug 2020 04:41:59 |
| User entered 'No (N)' | System | 19 Aug 2020 04:41:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:41:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '67d08138-2bcd-4da2-af87-2f8dd1d0e902' | System | 19 Aug 2020 04:41:59 |
| User entered '18 Aug 2020 23:41' | System | 19 Aug 2020 04:41:59 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '18 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '19 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 5' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:13:47', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c727d694-2338-4230-bee8-a96d83c6c832' | System | 20 Aug 2020 03:14:04 |
| User entered 'Yes (Y)' | System | 20 Aug 2020 03:14:04 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:13:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c727d694-2338-4230-bee8-a96d83c6c832' | System | 20 Aug 2020 03:14:04 |
| User entered '98.2' | System | 20 Aug 2020 03:14:04 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:13:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c727d694-2338-4230-bee8-a96d83c6c832' | System | 20 Aug 2020 03:14:04 |
| User entered 'No (N)' | System | 20 Aug 2020 03:14:04 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c727d694-2338-4230-bee8-a96d83c6c832' | System | 20 Aug 2020 03:14:04 |
| User entered '19 Aug 2020 22:14' | System | 20 Aug 2020 03:14:04 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '19 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '20 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 6' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:37:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '87a6faf8-c5a2-41e6-bc38-61fb5887934f' | System | 21 Aug 2020 02:38:13 |
| User entered 'Yes (Y)' | System | 21 Aug 2020 02:38:13 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '87a6faf8-c5a2-41e6-bc38-61fb5887934f' | System | 21 Aug 2020 02:38:13 |
| User entered '98.0' | System | 21 Aug 2020 02:38:13 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '87a6faf8-c5a2-41e6-bc38-61fb5887934f' | System | 21 Aug 2020 02:38:13 |
| User entered 'No (N)' | System | 21 Aug 2020 02:38:13 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '87a6faf8-c5a2-41e6-bc38-61fb5887934f' | System | 21 Aug 2020 02:38:13 |
| User entered '20 Aug 2020 21:38' | System | 21 Aug 2020 02:38:13 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '20 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '21 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 7' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1f75a43-588b-4516-92ea-e83c8b0b9e47' | System | 22 Aug 2020 05:04:53 |
| User entered 'Yes (Y)' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1f75a43-588b-4516-92ea-e83c8b0b9e47' | System | 22 Aug 2020 05:04:53 |
| User entered '99.9' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1f75a43-588b-4516-92ea-e83c8b0b9e47' | System | 22 Aug 2020 05:04:53 |
| User entered 'Yes (Y)' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated con med log' (Site from System). | | 16 Sep 2020 13:38:26 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1f75a43-588b-4516-92ea-e83c8b0b9e47' | System | 22 Aug 2020 05:04:53 |
| User entered '1' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1f75a43-588b-4516-92ea-e83c8b0b9e47' | System | 22 Aug 2020 05:04:53 |
| User entered '0' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1f75a43-588b-4516-92ea-e83c8b0b9e47' | System | 22 Aug 2020 05:04:53 |
| User entered '22 Aug 2020 00:04' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '21 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '22 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 22 Aug 2020 05:04:53 |
| User entered 'Day 8' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a39e57bb-5bd0-43da-839c-2540f423aeb0' | System | 23 Aug 2020 02:46:41 |
| User entered 'Yes (Y)' | System | 23 Aug 2020 02:46:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a39e57bb-5bd0-43da-839c-2540f423aeb0' | System | 23 Aug 2020 02:46:41 |
| User entered '98.9' | System | 23 Aug 2020 02:46:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a39e57bb-5bd0-43da-839c-2540f423aeb0' | System | 23 Aug 2020 02:46:41 |
| User entered 'Yes (Y)' | System | 23 Aug 2020 02:46:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated con med log' (Site from System). | | 16 Sep 2020 13:38:37 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a39e57bb-5bd0-43da-839c-2540f423aeb0' | System | 23 Aug 2020 02:46:41 |
| User entered '1' | System | 23 Aug 2020 02:46:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a39e57bb-5bd0-43da-839c-2540f423aeb0' User entered '0' | System | 23 Aug 2020 02:46:41 |
| | System | 23 Aug 2020 02:46:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a39e57bb-5bd0-43da-839c-2540f423aeb0' | System | 23 Aug 2020 02:46:41 |
| User entered '22 Aug 2020 21:46' | System | 23 Aug 2020 02:46:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '22 Aug 2020 12:00' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Aug 2020 11:59' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 22 Aug 2020 05:04:53 |
| User entered 'Day 9' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3467424d-7be3-4cfe-89ee-81d72fc2106e' | System | 24 Aug 2020 04:42:19 |
| User entered 'Yes (Y)' | System | 24 Aug 2020 04:42:19 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3467424d-7be3-4cfe-89ee-81d72fc2106e' | System | 24 Aug 2020 04:42:19 |
| User entered '98.9' | System | 24 Aug 2020 04:42:19 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3467424d-7be3-4cfe-89ee-81d72fc2106e' | System | 24 Aug 2020 04:42:19 |
| User entered 'No (N)' | System | 24 Aug 2020 04:42:19 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3467424d-7be3-4cfe-89ee-81d72fc2106e' | System | 24 Aug 2020 04:42:19 |
| User entered '23 Aug 2020 23:42' | System | 24 Aug 2020 04:42:19 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Aug 2020 12:00' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Aug 2020 11:59' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:16:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd0fd5289-b3bb-4c4d-8aaa-695a6670ddfc' | System | 15 Aug 2020 20:17:07 |
| User entered 'Does not interfere with activity (2)' | System | 15 Aug 2020 20:17:07 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:16:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd0fd5289-b3bb-4c4d-8aaa-695a6670ddfc' | System | 15 Aug 2020 20:17:07 |
| User entered 'No (N)' | System | 15 Aug 2020 20:17:07 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Is there any SWELLING/HARDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:16:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd0fd5289-b3bb-4c4d-8aaa-695a6670ddfc' | System | 15 Aug 2020 20:17:07 |
| User entered 'No (N)' | System | 15 Aug 2020 20:17:07 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:16:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd0fd5289-b3bb-4c4d-8aaa-695a6670ddfc' | System | 15 Aug 2020 20:17:07 |
| User entered 'None (1)' | System | 15 Aug 2020 20:17:07 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd0fd5289-b3bb-4c4d-8aaa-695a6670ddfc' | System | 15 Aug 2020 20:17:07 |
| User entered '15 Aug 2020 15:17' | System | 15 Aug 2020 20:17:07 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '15 Aug 2020 15:12' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '15 Aug 2020 17:42' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 1, after vaccination (at home)' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b49ca638-8c46-4ff1-8b27-3a9cb3471f25' | System | 16 Aug 2020 02:05:19 |
| User entered 'Does not interfere with activity (2)' | System | 16 Aug 2020 02:05:19 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b49ca638-8c46-4ff1-8b27-3a9cb3471f25' | System | 16 Aug 2020 02:05:19 |
| User entered 'No (N)' | System | 16 Aug 2020 02:05:19 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Is there any SWELLING/HARDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b49ca638-8c46-4ff1-8b27-3a9cb3471f25' | System | 16 Aug 2020 02:05:19 |
| User entered 'No (N)' | System | 16 Aug 2020 02:05:19 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:05:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b49ca638-8c46-4ff1-8b27-3a9cb3471f25' | System | 16 Aug 2020 02:05:19 |
| User entered 'Does not interfere with activity (2)' | System | 16 Aug 2020 02:05:19 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:05:18', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b49ca638-8c46-4ff1-8b27-3a9cb3471f25' | System | 16 Aug 2020 02:05:19 |
| User entered '15 Aug 2020 21:05' | System | 16 Aug 2020 02:05:19 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '15 Aug 2020 18:37' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 2' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c62b455a-8d84-43e2-ac9b-c7329ca10fa5' | System | 16 Aug 2020 20:57:55 |
| User entered 'Does not interfere with activity (2)' | System | 16 Aug 2020 20:57:55 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c62b455a-8d84-43e2-ac9b-c7329ca10fa5' | System | 16 Aug 2020 20:57:55 |
| User entered 'No (N)' | System | 16 Aug 2020 20:57:55 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c62b455a-8d84-43e2-ac9b-c7329ca10fa5' | System | 16 Aug 2020 20:57:55 |
| User entered 'No (N)' | System | 16 Aug 2020 20:57:55 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c62b455a-8d84-43e2-ac9b-c7329ca10fa5' | System | 16 Aug 2020 20:57:55 |
| User entered 'None (1)' | System | 16 Aug 2020 20:57:55 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c62b455a-8d84-43e2-ac9b-c7329ca10fa5' | System | 16 Aug 2020 20:57:55 |
| User entered '16 Aug 2020 15:57' | System | 16 Aug 2020 20:57:55 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '17 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 3' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5a20133c-d39b-4c51-9a54-f3332219d744' | System | 18 Aug 2020 02:50:41 |
| User entered 'Does not interfere with activity (2)' | System | 18 Aug 2020 02:50:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5a20133c-d39b-4c51-9a54-f3332219d744' | System | 18 Aug 2020 02:50:41 |
| User entered 'No (N)' | System | 18 Aug 2020 02:50:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5a20133c-d39b-4c51-9a54-f3332219d744' | System | 18 Aug 2020 02:50:41 |
| User entered 'No (N)' | System | 18 Aug 2020 02:50:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5a20133c-d39b-4c51-9a54-f3332219d744' | System | 18 Aug 2020 02:50:41 |
| User entered 'None (1)' | System | 18 Aug 2020 02:50:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5a20133c-d39b-4c51-9a54-f3332219d744' | System | 18 Aug 2020 02:50:41 |
| User entered '17 Aug 2020 21:50' | System | 18 Aug 2020 02:50:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '17 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '18 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 4' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f8767d77-a566-4a2b-aceb-f0e237e31bf4' | System | 19 Aug 2020 04:42:34 |
| User entered 'None (1)' | System | 19 Aug 2020 04:42:34 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f8767d77-a566-4a2b-aceb-f0e237e31bf4' | System | 19 Aug 2020 04:42:34 |
| User entered 'No (N)' | System | 19 Aug 2020 04:42:34 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f8767d77-a566-4a2b-aceb-f0e237e31bf4' | System | 19 Aug 2020 04:42:34 |
| User entered 'No (N)' | System | 19 Aug 2020 04:42:34 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:27', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f8767d77-a566-4a2b-aceb-f0e237e31bf4' | System | 19 Aug 2020 04:42:34 |
| User entered 'None (1)' | System | 19 Aug 2020 04:42:34 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f8767d77-a566-4a2b-aceb-f0e237e31bf4' | System | 19 Aug 2020 04:42:34 |
| User entered '18 Aug 2020 23:42' | System | 19 Aug 2020 04:42:34 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '18 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '19 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 5' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '61fcb639-bc80-481e-8a49-8fe6f856357f' | System | 20 Aug 2020 03:14:28 |
| User entered 'None (1)' | System | 20 Aug 2020 03:14:28 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '61fcb639-bc80-481e-8a49-8fe6f856357f' | System | 20 Aug 2020 03:14:28 |
| User entered 'No (N)' | System | 20 Aug 2020 03:14:28 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '61fcb639-bc80-481e-8a49-8fe6f856357f' | System | 20 Aug 2020 03:14:28 |
| User entered 'No (N)' | System | 20 Aug 2020 03:14:28 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '61fcb639-bc80-481e-8a49-8fe6f856357f' | System | 20 Aug 2020 03:14:28 |
| User entered 'None (1)' | System | 20 Aug 2020 03:14:28 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '61fcb639-bc80-481e-8a49-8fe6f856357f' | System | 20 Aug 2020 03:14:28 |
| User entered '19 Aug 2020 22:14' | System | 20 Aug 2020 03:14:28 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '19 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '20 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 6' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f00d3131-01bc-49b3-8966-1d7c50ccf2b7' | System | 21 Aug 2020 02:38:35 |
| User entered 'None (1)' | System | 21 Aug 2020 02:38:35 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f00d3131-01bc-49b3-8966-1d7c50ccf2b7' | System | 21 Aug 2020 02:38:35 |
| User entered 'No (N)' | System | 21 Aug 2020 02:38:35 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f00d3131-01bc-49b3-8966-1d7c50ccf2b7' | System | 21 Aug 2020 02:38:35 |
| User entered 'No (N)' | System | 21 Aug 2020 02:38:35 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:27', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f00d3131-01bc-49b3-8966-1d7c50ccf2b7' | System | 21 Aug 2020 02:38:35 |
| User entered 'None (1)' | System | 21 Aug 2020 02:38:35 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f00d3131-01bc-49b3-8966-1d7c50ccf2b7' | System | 21 Aug 2020 02:38:35 |
| User entered '20 Aug 2020 21:38' | System | 21 Aug 2020 02:38:35 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '20 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '21 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 7' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4451e241-b091-49f7-91b3-3e45902ecf45' | System | 22 Aug 2020 05:04:29 |
| User entered 'None (1)' | System | 22 Aug 2020 05:04:29 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:18', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4451e241-b091-49f7-91b3-3e45902ecf45' | System | 22 Aug 2020 05:04:29 |
| User entered 'No (N)' | System | 22 Aug 2020 05:04:29 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4451e241-b091-49f7-91b3-3e45902ecf45' | System | 22 Aug 2020 05:04:29 |
| User entered 'No (N)' | System | 22 Aug 2020 05:04:29 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4451e241-b091-49f7-91b3-3e45902ecf45' | System | 22 Aug 2020 05:04:29 |
| User entered 'None (1)' | System | 22 Aug 2020 05:04:29 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:27', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4451e241-b091-49f7-91b3-3e45902ecf45' | System | 22 Aug 2020 05:04:29 |
| User entered '22 Aug 2020 00:04' | System | 22 Aug 2020 05:04:29 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '21 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '22 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730' | System | 15 Aug 2020 20:17:53 |
| User entered 'None (0)' | System | 15 Aug 2020 20:17:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730' | System | 15 Aug 2020 20:17:53 |
| User entered 'None (0)' | System | 15 Aug 2020 20:17:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:29', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730' | System | 15 Aug 2020 20:17:53 |
| User entered 'None (0)' | System | 15 Aug 2020 20:17:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730' | System | 15 Aug 2020 20:17:53 |
| User entered 'None (0)' | System | 15 Aug 2020 20:17:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:35', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730' | System | 15 Aug 2020 20:17:53 |
| User entered 'None (0)' | System | 15 Aug 2020 20:17:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730' | System | 15 Aug 2020 20:17:53 |
| User entered 'None (0)' | System | 15 Aug 2020 20:17:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730' | System | 15 Aug 2020 20:17:53 |
| User entered 'No (N)' | System | 15 Aug 2020 20:17:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730' | System | 15 Aug 2020 20:17:53 |
| User entered '15 Aug 2020 15:17' | System | 15 Aug 2020 20:17:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '15 Aug 2020 15:12' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '15 Aug 2020 17:42' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 1, after vaccination (at home)' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:03:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9' | System | 16 Aug 2020 02:04:26 |
| User entered 'None (0)' | System | 16 Aug 2020 02:04:26 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:03:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9' | System | 16 Aug 2020 02:04:26 |
| User entered 'No interference with activity (1)' | System | 16 Aug 2020 02:04:26 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9' | System | 16 Aug 2020 02:04:26 |
| User entered 'None (0)' | System | 16 Aug 2020 02:04:26 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9' | System | 16 Aug 2020 02:04:26 |
| User entered 'None (0)' | System | 16 Aug 2020 02:04:26 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9' | System | 16 Aug 2020 02:04:26 |
| User entered 'None (0)' | System | 16 Aug 2020 02:04:26 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9' | System | 16 Aug 2020 02:04:26 |
| User entered 'None (0)' | System | 16 Aug 2020 02:04:26 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9' | System | 16 Aug 2020 02:04:26 |
| User entered 'No (N)' | System | 16 Aug 2020 02:04:26 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9' | System | 16 Aug 2020 02:04:26 |
| User entered '15 Aug 2020 21:04' | System | 16 Aug 2020 02:04:26 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '15 Aug 2020 18:37' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 2' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452' | System | 16 Aug 2020 20:57:14 |
| User entered 'No interference with activity (1)' | System | 16 Aug 2020 20:57:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452' | System | 16 Aug 2020 20:57:14 |
| User entered 'No interference with activity (1)' | System | 16 Aug 2020 20:57:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452' | System | 16 Aug 2020 20:57:14 |
| User entered 'No interference with activity (1)' | System | 16 Aug 2020 20:57:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452' | System | 16 Aug 2020 20:57:14 |
| User entered 'No interference with activity (1)' | System | 16 Aug 2020 20:57:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452' | System | 16 Aug 2020 20:57:14 |
| User entered 'None (0)' | System | 16 Aug 2020 20:57:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452' | System | 16 Aug 2020 20:57:14 |
| User entered 'None (0)' | System | 16 Aug 2020 20:57:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452' | System | 16 Aug 2020 20:57:14 |
| User entered 'No (N)' | System | 16 Aug 2020 20:57:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452' | System | 16 Aug 2020 20:57:14 |
| User entered '16 Aug 2020 15:57' | System | 16 Aug 2020 20:57:14 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '17 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 3' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7' | System | 18 Aug 2020 02:51:22 |
| User entered 'No interference with activity (1)' | System | 18 Aug 2020 02:51:22 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7' | System | 18 Aug 2020 02:51:22 |
| User entered 'No interference with activity (1)' | System | 18 Aug 2020 02:51:22 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7' | System | 18 Aug 2020 02:51:22 |
| User entered 'None (0)' | System | 18 Aug 2020 02:51:22 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:51:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7' | System | 18 Aug 2020 02:51:22 |
| User entered 'None (0)' | System | 18 Aug 2020 02:51:22 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:51:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7' | System | 18 Aug 2020 02:51:22 |
| User entered 'None (0)' | System | 18 Aug 2020 02:51:22 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:51:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7' | System | 18 Aug 2020 02:51:22 |
| User entered 'None (0)' | System | 18 Aug 2020 02:51:22 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:51:18', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7' | System | 18 Aug 2020 02:51:22 |
| User entered 'No (N)' | System | 18 Aug 2020 02:51:22 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:51:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7' | System | 18 Aug 2020 02:51:22 |
| User entered '17 Aug 2020 21:51' | System | 18 Aug 2020 02:51:22 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '17 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '18 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 4' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9' | System | 19 Aug 2020 04:43:13 |
| User entered 'None (0)' | System | 19 Aug 2020 04:43:13 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9' | System | 19 Aug 2020 04:43:13 |
| User entered 'Some interference with activity (2)' | System | 19 Aug 2020 04:43:13 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9' | System | 19 Aug 2020 04:43:13 |
| User entered 'None (0)' | System | 19 Aug 2020 04:43:13 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9' | System | 19 Aug 2020 04:43:13 |
| User entered 'None (0)' | System | 19 Aug 2020 04:43:13 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9' | System | 19 Aug 2020 04:43:13 |
| User entered 'None (0)' | System | 19 Aug 2020 04:43:13 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9' | System | 19 Aug 2020 04:43:13 |
| User entered 'None (0)' | System | 19 Aug 2020 04:43:13 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:43:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9' | System | 19 Aug 2020 04:43:13 |
| User entered 'No (N)' | System | 19 Aug 2020 04:43:13 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:43:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9' | System | 19 Aug 2020 04:43:13 |
| User entered '18 Aug 2020 23:43' | System | 19 Aug 2020 04:43:13 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '18 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '19 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 5' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129' | System | 20 Aug 2020 03:15:04 |
| User entered 'None (0)' | System | 20 Aug 2020 03:15:04 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129' | System | 20 Aug 2020 03:15:04 |
| User entered 'No interference with activity (1)' | System | 20 Aug 2020 03:15:04 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129' | System | 20 Aug 2020 03:15:04 |
| User entered 'None (0)' | System | 20 Aug 2020 03:15:04 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129' | System | 20 Aug 2020 03:15:04 |
| User entered 'None (0)' | System | 20 Aug 2020 03:15:04 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129' | System | 20 Aug 2020 03:15:04 |
| User entered 'None (0)' | System | 20 Aug 2020 03:15:04 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129' | System | 20 Aug 2020 03:15:04 |
| User entered 'None (0)' | System | 20 Aug 2020 03:15:04 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129' | System | 20 Aug 2020 03:15:04 |
| User entered 'No (N)' | System | 20 Aug 2020 03:15:04 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129' | System | 20 Aug 2020 03:15:04 |
| User entered '19 Aug 2020 22:14' | System | 20 Aug 2020 03:15:04 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '19 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '20 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 6' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:35', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6' | System | 21 Aug 2020 02:39:08 |
| User entered 'None (0)' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6' | System | 21 Aug 2020 02:39:08 |
| User entered 'Some interference with activity (2)' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6' | System | 21 Aug 2020 02:39:08 |
| User entered 'None (0)' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6' | System | 21 Aug 2020 02:39:08 |
| User entered 'None (0)' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6' | System | 21 Aug 2020 02:39:08 |
| User entered 'None (0)' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6' | System | 21 Aug 2020 02:39:08 |
| User entered 'None (0)' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6' | System | 21 Aug 2020 02:39:08 |
| User entered 'No (N)' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:39:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6' | System | 21 Aug 2020 02:39:08 |
| User entered '20 Aug 2020 21:39' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '20 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '21 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 7' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec' | System | 22 Aug 2020 05:05:15 |
| User entered 'None (0)' | System | 22 Aug 2020 05:05:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:58', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec' | System | 22 Aug 2020 05:05:15 |
| User entered 'No interference with activity (1)' | System | 22 Aug 2020 05:05:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec' | System | 22 Aug 2020 05:05:15 |
| User entered 'None (0)' | System | 22 Aug 2020 05:05:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:05:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec' | System | 22 Aug 2020 05:05:15 |
| User entered 'None (0)' | System | 22 Aug 2020 05:05:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:05:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec' | System | 22 Aug 2020 05:05:15 |
| User entered 'None (0)' | System | 22 Aug 2020 05:05:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:05:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec' | System | 22 Aug 2020 05:05:15 |
| User entered 'None (0)' | System | 22 Aug 2020 05:05:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:05:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec' | System | 22 Aug 2020 05:05:15 |
| User entered 'No (N)' | System | 22 Aug 2020 05:05:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:05:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec' | System | 22 Aug 2020 05:05:15 |
| User entered '22 Aug 2020 00:05' | System | 22 Aug 2020 05:05:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '21 Aug 2020 12:00' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '22 Aug 2020 11:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 21 Aug 2020 02:39:08 |
| User entered 'Day 8' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '30245d40-97ce-4433-9eaf-6021f3b3d793' | System | 23 Aug 2020 02:46:52 |
| User entered 'No interference with activity (1)' | System | 23 Aug 2020 02:46:52 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '30245d40-97ce-4433-9eaf-6021f3b3d793' | System | 23 Aug 2020 02:46:52 |
| User entered '22 Aug 2020 21:46' | System | 23 Aug 2020 02:46:52 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '22 Aug 2020 12:00' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Aug 2020 11:59' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 22 Aug 2020 05:05:15 |
| User entered 'Day 9' | System | 22 Aug 2020 05:05:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '86dcfb08-baeb-4dfe-a3e3-c78fd74958f3' | System | 24 Aug 2020 04:42:30 |
| User entered 'Some interference with activity (2)' | System | 24 Aug 2020 04:42:30 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '86dcfb08-baeb-4dfe-a3e3-c78fd74958f3' | System | 24 Aug 2020 04:42:30 |
| User entered '23 Aug 2020 23:42' | System | 24 Aug 2020 04:42:30 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Aug 2020 12:00' | System | 22 Aug 2020 05:05:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Aug 2020 11:59' | System | 22 Aug 2020 05:05:15 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 23 Aug 2020 02:46:52 |
| User entered 'Day 10' | System | 23 Aug 2020 02:46:52 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Aug 2020 12:00' | System | 23 Aug 2020 02:46:52 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Aug 2020 11:59' | System | 23 Aug 2020 02:46:52 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 24 Aug 2020 04:42:30 |
| User entered 'Day 11' | System | 24 Aug 2020 04:42:30 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-25T23:56:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'cc841b5a-bbfe-4bb1-b516-915f46101635' | System | 26 Aug 2020 04:56:58 |
| User entered 'No interference with activity (1)' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-25T23:56:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'cc841b5a-bbfe-4bb1-b516-915f46101635' | System | 26 Aug 2020 04:56:58 |
| User entered '25 Aug 2020 23:56' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Aug 2020 12:00' | System | 24 Aug 2020 04:42:30 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Aug 2020 11:59' | System | 24 Aug 2020 04:42:30 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 26 Aug 2020 04:56:58 |
| User entered 'Day 12' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Aug 2020 12:00' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Aug 2020 11:59' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 26 Aug 2020 04:56:58 |
| User entered 'Day 13' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-28T00:30:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '301f67bd-b6a9-44c4-87f4-20f9c60cb09a' | System | 28 Aug 2020 05:30:58 |
| User entered 'Some interference with activity (2)' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-28T00:30:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '301f67bd-b6a9-44c4-87f4-20f9c60cb09a' | System | 28 Aug 2020 05:30:58 |
| User entered '28 Aug 2020 00:30' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 28 Aug 2020 05:30:58 |
| User entered 'Day 14' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-29T00:35:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6cab6df7-e668-4cfc-a6f9-674e1cdc032a' | System | 29 Aug 2020 05:35:22 |
| User entered 'No interference with activity (1)' | System | 29 Aug 2020 05:35:22 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-29T00:35:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6cab6df7-e668-4cfc-a6f9-674e1cdc032a' | System | 29 Aug 2020 05:35:22 |
| User entered '29 Aug 2020 00:35' | System | 29 Aug 2020 05:35:22 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Aug 2020 12:00' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Aug 2020 11:59' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 28 Aug 2020 05:30:58 |
| User entered 'Day 15' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-29T21:39:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '303137c3-3fcd-4552-9438-93feee8606b4' | System | 30 Aug 2020 02:39:41 |
| User entered 'None (0)' | System | 30 Aug 2020 02:39:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-29T21:39:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '303137c3-3fcd-4552-9438-93feee8606b4' | System | 30 Aug 2020 02:39:41 |
| User entered '29 Aug 2020 21:39' | System | 30 Aug 2020 02:39:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Aug 2020 12:00' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Aug 2020 11:59' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 21 Aug 2020 02:39:08 |
| User entered 'Day 8' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c54f8480-a27c-427e-bb61-ae4a5e0843c' | System | 23 Aug 2020 02:47:01 |
| User entered 'No (N)' | System | 23 Aug 2020 02:47:01 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c54f8480-a27c-427e-bb61-ae4a5e0843c' | System | 23 Aug 2020 02:47:01 |
| User entered '22 Aug 2020 21:46' | System | 23 Aug 2020 02:47:01 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '22 Aug 2020 12:00' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Aug 2020 11:59' | System | 21 Aug 2020 02:39:08 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 22 Aug 2020 05:04:53 |
| User entered 'Day 9' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'eb9608b6-0c88-4421-83ad-2fafa34d6540' | System | 24 Aug 2020 04:42:41 |
| User entered 'No (N)' | System | 24 Aug 2020 04:42:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'eb9608b6-0c88-4421-83ad-2fafa34d6540' | System | 24 Aug 2020 04:42:41 |
| User entered '23 Aug 2020 23:42' | System | 24 Aug 2020 04:42:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Aug 2020 12:00' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Aug 2020 11:59' | System | 22 Aug 2020 05:04:53 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 23 Aug 2020 02:46:41 |
| User entered 'Day 10' | System | 23 Aug 2020 02:46:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Aug 2020 12:00' | System | 23 Aug 2020 02:46:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Aug 2020 11:59' | System | 23 Aug 2020 02:46:41 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 24 Aug 2020 04:42:30 |
| User entered 'Day 11' | System | 24 Aug 2020 04:42:30 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-25T23:57:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c9f3a042-6053-4017-bf7e-6282f084c4c6' | System | 26 Aug 2020 04:57:09 |
| User entered 'No (N)' | System | 26 Aug 2020 04:57:09 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-25T23:57:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c9f3a042-6053-4017-bf7e-6282f084c4c6' | System | 26 Aug 2020 04:57:09 |
| User entered '25 Aug 2020 23:57' | System | 26 Aug 2020 04:57:09 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Aug 2020 12:00' | System | 24 Aug 2020 04:42:30 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Aug 2020 11:59' | System | 24 Aug 2020 04:42:30 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 26 Aug 2020 04:56:58 |
| User entered 'Day 12' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Aug 2020 12:00' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Aug 2020 11:59' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 26 Aug 2020 04:56:58 |
| User entered 'Day 13' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-28T00:31:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '519b7892-a326-4075-ad97-1538d81bcb32' | System | 28 Aug 2020 05:31:11 |
| User entered 'No (N)' | System | 28 Aug 2020 05:31:11 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-28T00:31:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '519b7892-a326-4075-ad97-1538d81bcb32' | System | 28 Aug 2020 05:31:11 |
| User entered '28 Aug 2020 00:31' | System | 28 Aug 2020 05:31:11 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 04:56:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 28 Aug 2020 05:30:58 |
| User entered 'Day 14' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-29T00:35:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'de9b301f-a027-46dc-8f8b-071358fb78cf' | System | 29 Aug 2020 05:35:28 |
| User entered 'No (N)' | System | 29 Aug 2020 05:35:28 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-29T00:35:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'de9b301f-a027-46dc-8f8b-071358fb78cf' | System | 29 Aug 2020 05:35:28 |
| User entered '29 Aug 2020 00:35' | System | 29 Aug 2020 05:35:28 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Aug 2020 12:00' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Aug 2020 11:59' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 28 Aug 2020 05:30:58 |
| User entered 'Day 15' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-29T21:39:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7abe10f9-5685-4f82-903a-05052186d626' | System | 30 Aug 2020 02:39:47 |
| User entered 'No (N)' | System | 30 Aug 2020 02:39:47 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-29T21:39:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7abe10f9-5685-4f82-903a-05052186d626' | System | 30 Aug 2020 02:39:47 |
| User entered '29 Aug 2020 21:39' | System | 30 Aug 2020 02:39:47 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Aug 2020 12:00' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Aug 2020 11:59' | System | 28 Aug 2020 05:30:58 |

US3272169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:53:36 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 01 Sep 2020 15:04:27 |

US3272169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:53:36 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '24 Aug 2020' | (b) (4), (b) (6) | 01 Sep 2020 15:04:27 |

US3272169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:53:36 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 01 Sep 2020 15:04:27 |

US3272169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:53:36 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 01 Sep 2020 15:04:27 |

US3272169

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:53:36 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 01 Sep 2020 15:04:31 |

US3272169

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:53:36 |
| User entered 'I' | System | 01 Sep 2020 15:04:31 |

US3272169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:03:20 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 01 Sep 2020 15:04:40 |

US3272169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:03:20 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '31 Aug 2020' | (b) (4), (b) (6) | 01 Sep 2020 15:04:40 |

US3272169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:03:20 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 01 Sep 2020 15:04:40 |

US3272169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:03:20 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 01 Sep 2020 15:04:40 |

US3272169

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:03:20 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 01 Sep 2020 15:04:44 |

US3272169

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:03:20 |
| User entered 'I' | System | 01 Sep 2020 15:04:44 |

US3272169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:42:12 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Sep 2020 20:25:18 |

US3272169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:42:12 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4), (b) (6) | 30 Dec 2020 11:39:30 |
| Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' | (b) (4), (b) (6) | 28 Dec 2020 15:59:57 |
| answered with 'data is correct' (Site from System). | | |
| User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 28 Dec 2020 15:59:29 |
| User entered '09 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Dec 2020 15:59:29 |
| User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 09 Sep 2020 20:25:29 |
| Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' | System | 09 Sep 2020 20:25:29 |
| answered by data change (Site from System). | | |
| User entered '08 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Sep 2020 20:25:29 |
| User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 09 Sep 2020 20:25:18 |
| User entered '09 Sep 2020' | (b) (4), (b) (6) | 09 Sep 2020 20:25:18 |

US3272169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:42:12 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 09 Sep 2020 20:25:18 |

US3272169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:42:12 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 09 Sep 2020 20:25:18 |

US3272169

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:42:12 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Sep 2020 20:25:35 |

US3272169

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:42:12 |
| User entered 'I' | System | 09 Sep 2020 20:25:35 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 17:49:58 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '16 Sep 2020' | (b) (4), (b) (6) | 16 Sep 2020 17:49:58 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 16 Sep 2020 17:49:58 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User entered 'VISIT2' | System | 16 Sep 2020 17:49:58 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User accepted default value 'Pre-Dose (PREDOSE)' | | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '16 Sep 2020' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '11:15' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User entered '16 Sep 2020 11:15' | System | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '36.4' C | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '66' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User entered 'bpm' | System | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '12' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User entered 'breaths/min' | System | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '84' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User entered 'mmHg' | System | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '65' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User entered 'mmHg' | System | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User accepted default value 'Post-Dose (POSTDOSE)' | | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '16 Sep 2020' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '12:26' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User entered '16 Sep 2020 12:26' | System | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '36.6' C | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '68' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User entered 'bpm' | System | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '16' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User entered 'breaths/min' | System | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '81' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User entered 'mmHg' | System | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '65' | (b) (4), (b) (6) | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User entered 'mmHg' | System | 16 Sep 2020 17:50:44 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:09

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 17:50:50 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:09

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '16 Sep 2020' | (b) (4), (b) (6) | 16 Sep 2020 17:50:50 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 17:06:49 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 17:06:49 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 17:06:49 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '16 Sep 2020' | (b) (4), (b) (6) | 16 Sep 2020 17:06:49 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '12:06' | (b) (4), (b) (6) | 16 Sep 2020 17:06:49 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User entered '16 Sep 2020 12:06' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6) | 16 Sep 2020 17:06:49 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User entered 'ONCE' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:09

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User entered 'INTRAMUSCULAR' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 17:51:10 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '16 Sep 2020' | (b) (4), (b) (6) | 16 Sep 2020 17:51:10 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '11:20' | (b) (4), (b) (6) | 16 Sep 2020 17:51:10 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:39 |
| User entered '16 Sep 2020 11:20' | System | 16 Sep 2020 17:51:10 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:21:09

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '16 Sep 2020' | (b) (4), (b) (6) | 16 Sep 2020 17:51:19 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:09

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User accepted default value 'Nasopharyngeal Swab (NASAL1)' | | 16 Sep 2020 17:51:19 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:09

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 17:51:19 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:09

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '11:25' | (b) (4), (b) (6) | 16 Sep 2020 17:51:19 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:09

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User entered '16 Sep 2020 11:25' | System | 16 Sep 2020 17:51:19 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:09

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | | 16 Sep 2020 17:51:19 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:09

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Sep 2020 17:51:19 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:09

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 17:51:19 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:09

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User entered empty. | System | 16 Sep 2020 17:51:19 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 17:05:54 |

US3272169

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:57:29 |
| User entered 'I' | System | 16 Sep 2020 17:05:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T12:27:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5384f25d-b698-41bc-824a-8683dc5138cc' | System | 16 Sep 2020 17:28:07 |
| User entered 'Yes (Y)' | System | 16 Sep 2020 17:28:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T12:27:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5384f25d-b698-41bc-824a-8683dc5138cc' User entered '98.0' | System | 16 Sep 2020 17:28:07 |
| | System | 16 Sep 2020 17:28:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T12:27:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5384f25d-b698-41bc-824a-8683dc5138cc' | System | 16 Sep 2020 17:28:07 |
| User entered 'No (N)' | System | 16 Sep 2020 17:28:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T12:28:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5384f25d-b698-41bc-824a-8683dc5138cc' | System | 16 Sep 2020 17:28:07 |
| User entered '16 Sep 2020 12:28' | System | 16 Sep 2020 17:28:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Sep 2020 12:26' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Sep 2020 14:56' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 1, after vaccination (at home)' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:48:18', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ea95aa1f-fc97-4dae-bde0-d033465a5cad' | System | 17 Sep 2020 02:48:36 |
| User entered 'Yes (Y)' | System | 17 Sep 2020 02:48:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:48:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ea95aa1f-fc97-4dae-bde0-d033465a5cad' | System | 17 Sep 2020 02:48:36 |
| User entered '98.9' | System | 17 Sep 2020 02:48:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:48:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ea95aa1f-fc97-4dae-bde0-d033465a5cad' | System | 17 Sep 2020 02:48:36 |
| User entered 'No (N)' | System | 17 Sep 2020 02:48:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:48:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ea95aa1f-fc97-4dae-bde0-d033465a5cad' | System | 17 Sep 2020 02:48:36 |
| User entered '16 Sep 2020 21:48' | System | 17 Sep 2020 02:48:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Sep 2020 15:51' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '17 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 2' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '85e4f5a2-9bf9-4c1e-965c-b5e3124ce412' | System | 18 Sep 2020 02:24:39 |
| User entered 'Yes (Y)' | System | 18 Sep 2020 02:24:39 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '85e4f5a2-9bf9-4c1e-965c-b5e3124ce412' | System | 18 Sep 2020 02:24:39 |
| User entered '99.1' | System | 18 Sep 2020 02:24:39 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '85e4f5a2-9bf9-4c1e-965c-b5e3124ce412' | System | 18 Sep 2020 02:24:39 |
| User entered 'Yes (Y)' | System | 18 Sep 2020 02:24:39 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'pt contacted waiting on response ' (Site from System). | (b) (4) | 04 Nov 2020 23:08:13 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' | Ashley Bell (b) (4) | 18 Sep 2020 19:20:45 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '85e4f5a2-9bf9-4c1e-965c-b5e3124ce412' | System | 18 Sep 2020 02:24:39 |
| User entered '1' | System | 18 Sep 2020 02:24:39 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '85e4f5a2-9bf9-4c1e-965c-b5e3124ce412' | System | 18 Sep 2020 02:24:39 |
| User entered '0' | System | 18 Sep 2020 02:24:39 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '85e4f5a2-9bf9-4c1e-965c-b5e3124ce412' | System | 18 Sep 2020 02:24:39 |
| User entered '17 Sep 2020 21:24' | System | 18 Sep 2020 02:24:39 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '17 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '18 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 3' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:38:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4f9436dc-5162-4898-bd90-b244525d0a00' | System | 19 Sep 2020 04:39:10 |
| User entered 'Yes (Y)' | System | 19 Sep 2020 04:39:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:38:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4f9436dc-5162-4898-bd90-b244525d0a00' | System | 19 Sep 2020 04:39:10 |
| User entered '99.3' | System | 19 Sep 2020 04:39:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4f9436dc-5162-4898-bd90-b244525d0a00' | System | 19 Sep 2020 04:39:10 |
| User entered 'Yes (Y)' | System | 19 Sep 2020 04:39:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated con meds' (Site from System). | | 04 Nov 2020 23:08:34 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4f9436dc-5162-4898-bd90-b244525d0a00' | System | 19 Sep 2020 04:39:10 |
| User entered '1' | System | 19 Sep 2020 04:39:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4f9436dc-5162-4898-bd90-b244525d0a00' | System | 19 Sep 2020 04:39:10 |
| User entered '0' | System | 19 Sep 2020 04:39:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4f9436dc-5162-4898-bd90-b244525d0a00' | System | 19 Sep 2020 04:39:10 |
| User entered '18 Sep 2020 23:39' | System | 19 Sep 2020 04:39:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 4' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4c45a08-2c7c-4de1-8d25-605f244b9268' | System | 20 Sep 2020 02:49:33 |
| User entered 'Yes (Y)' | System | 20 Sep 2020 02:49:33 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4c45a08-2c7c-4de1-8d25-605f244b9268' | System | 20 Sep 2020 02:49:33 |
| User entered '98.7' | System | 20 Sep 2020 02:49:33 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4c45a08-2c7c-4de1-8d25-605f244b9268' | System | 20 Sep 2020 02:49:33 |
| User entered 'Yes (Y)' | System | 20 Sep 2020 02:49:33 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated con meds' (Site from System). | | 04 Nov 2020 23:08:53 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4c45a08-2c7c-4de1-8d25-605f244b9268' | System | 20 Sep 2020 02:49:33 |
| User entered '1' | System | 20 Sep 2020 02:49:33 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4c45a08-2c7c-4de1-8d25-605f244b9268' | System | 20 Sep 2020 02:49:33 |
| User entered '0' | System | 20 Sep 2020 02:49:33 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4c45a08-2c7c-4de1-8d25-605f244b9268' | System | 20 Sep 2020 02:49:33 |
| User entered '19 Sep 2020 21:49' | System | 20 Sep 2020 02:49:33 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '19 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '20 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 5' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '19987506-ec34-48fd-a126-7b504978bdf7' | System | 21 Sep 2020 04:58:32 |
| User entered 'Yes (Y)' | System | 21 Sep 2020 04:58:32 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '19987506-ec34-48fd-a126-7b504978bdf7' | System | 21 Sep 2020 04:58:32 |
| User entered '98.9' | System | 21 Sep 2020 04:58:32 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '19987506-ec34-48fd-a126-7b504978bdf7' | System | 21 Sep 2020 04:58:32 |
| User entered 'Yes (Y)' | System | 21 Sep 2020 04:58:32 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated con meds' (Site from System). | | 04 Nov 2020 23:09:12 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '19987506-ec34-48fd-a126-7b504978bdf7' | System | 21 Sep 2020 04:58:32 |
| User entered '1' | System | 21 Sep 2020 04:58:32 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '19987506-ec34-48fd-a126-7b504978bdf7' | System | 21 Sep 2020 04:58:32 |
| User entered '0' | System | 21 Sep 2020 04:58:32 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:27', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '19987506-ec34-48fd-a126-7b504978bdf7' | System | 21 Sep 2020 04:58:32 |
| User entered '20 Sep 2020 23:58' | System | 21 Sep 2020 04:58:32 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '20 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '21 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 6' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e808397-393b-43da-970a-b91273ac2110' | System | 22 Sep 2020 02:31:45 |
| User entered 'Yes (Y)' | System | 22 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e808397-393b-43da-970a-b91273ac2110' | System | 22 Sep 2020 02:31:45 |
| User entered '99.0' | System | 22 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e808397-393b-43da-970a-b91273ac2110' | System | 22 Sep 2020 02:31:45 |
| User entered 'Yes (Y)' | System | 22 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System). | (b) (4) | 04 Nov 2020 23:09:29 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | Kayla Flege (b) (4) | 25 Sep 2020 19:22:20 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e808397-393b-43da-970a-b91273ac2110' | (b) (4) | |
| User entered '1' | System | 22 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e808397-393b-43da-970a-b91273ac2110' | System | 22 Sep 2020 02:31:45 |
| User entered '0' | System | 22 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e808397-393b-43da-970a-b91273ac2110' | System | 22 Sep 2020 02:31:45 |
| User entered '21 Sep 2020 21:31' | System | 22 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '21 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '22 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 7' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:19:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '81623b35-6d2f-477a-a94c-bf7ffc4efcc3' | System | 23 Sep 2020 04:20:03 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 04:20:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:19:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '81623b35-6d2f-477a-a94c-bf7ffc4efcc3' | System | 23 Sep 2020 04:20:03 |
| User entered '99.0' | System | 23 Sep 2020 04:20:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:19:47', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '81623b35-6d2f-477a-a94c-bf7ffc4efcc3' | System | 23 Sep 2020 04:20:03 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 04:20:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System). | (b) (4) | 04 Nov 2020 23:09:53 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | Kayla Flege (b) (4) | 25 Sep 2020 19:22:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:19:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '81623b35-6d2f-477a-a94c-bf7ffc4efcc3' | (b) (4) | |
| User entered '1' | System | 23 Sep 2020 04:20:03 |
| | System | 23 Sep 2020 04:20:03 |
| | System | 23 Sep 2020 04:20:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:19:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '81623b35-6d2f-477a-a94c-bf7ffc4efcc3' | System | 23 Sep 2020 04:20:03 |
| User entered '0' | System | 23 Sep 2020 04:20:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:19:58', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '81623b35-6d2f-477a-a94c-bf7ffc4efcc3' | System | 23 Sep 2020 04:20:03 |
| User entered '22 Sep 2020 23:19' | System | 23 Sep 2020 04:20:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '22 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 22 Sep 2020 02:31:45 |
| User entered 'Day 8' | System | 22 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T21:59:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '88b6982e-6c7c-4c23-b2f9-ae417c63fc5a' | System | 24 Sep 2020 03:00:24 |
| User entered 'Yes (Y)' | System | 24 Sep 2020 03:00:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T21:59:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '88b6982e-6c7c-4c23-b2f9-ae417c63fc5a' | System | 24 Sep 2020 03:00:24 |
| User entered '98.9' | System | 24 Sep 2020 03:00:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T21:59:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '88b6982e-6c7c-4c23-b2f9-ae417c63fc5a' | System | 24 Sep 2020 03:00:24 |
| User entered 'Yes (Y)' | System | 24 Sep 2020 03:00:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System). | (b) (4) | 04 Nov 2020 23:10:11 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | Kayla Flege (b) (4) | 25 Sep 2020 19:22:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T21:59:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '88b6982e-6c7c-4c23-b2f9-ae417c63fc5a' | (b) (4) | |
| User entered '1' | System | 24 Sep 2020 03:00:24 |
| | System | 24 Sep 2020 03:00:24 |
| | System | 24 Sep 2020 03:00:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T21:59:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '88b6982e-6c7c-4c23-b2f9-ae417c63fc5a' | System | 24 Sep 2020 03:00:24 |
| User entered '0' | System | 24 Sep 2020 03:00:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T21:59:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '88b6982e-6c7c-4c23-b2f9-ae417c63fc5a' | System | 24 Sep 2020 03:00:24 |
| User entered '23 Sep 2020 21:59' | System | 24 Sep 2020 03:00:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 23 Sep 2020 04:20:03 |
| User entered 'Day 9' | System | 23 Sep 2020 04:20:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:31:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '49ba2e32-4475-491a-952b-2832be941dc9' | System | 25 Sep 2020 03:32:16 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 03:32:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '49ba2e32-4475-491a-952b-2832be941dc9' | System | 25 Sep 2020 03:32:16 |
| User entered '99.0' | System | 25 Sep 2020 03:32:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '49ba2e32-4475-491a-952b-2832be941dc9' | System | 25 Sep 2020 03:32:16 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 03:32:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System). | (b) (4) | 04 Nov 2020 23:10:30 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' | Kayla Flege (b) (4) | 25 Sep 2020 19:22:46 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '49ba2e32-4475-491a-952b-2832be941dc9' | (b) (4) | |
| User entered '1' | System | 25 Sep 2020 03:32:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '49ba2e32-4475-491a-952b-2832be941dc9' | System | 25 Sep 2020 03:32:16 |
| User entered '0' | System | 25 Sep 2020 03:32:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '49ba2e32-4475-491a-952b-2832be941dc9' | System | 25 Sep 2020 03:32:16 |
| User entered '24 Sep 2020 22:32' | System | 25 Sep 2020 03:32:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Sep 2020 12:00' | System | 23 Sep 2020 04:20:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Sep 2020 11:59' | System | 23 Sep 2020 04:20:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 24 Sep 2020 03:00:24 |
| User entered 'Day 10' | System | 24 Sep 2020 03:00:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8593fe65-33ce-428b-8a1b-b350f7f66af3' | System | 26 Sep 2020 04:20:59 |
| User entered 'Yes (Y)' | System | 26 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8593fe65-33ce-428b-8a1b-b350f7f66af3' | System | 26 Sep 2020 04:20:59 |
| User entered '99.9' | System | 26 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8593fe65-33ce-428b-8a1b-b350f7f66af3' | System | 26 Sep 2020 04:20:59 |
| User entered 'Yes (Y)' | System | 26 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con meds updated' (Site from System). | | 04 Nov 2020 23:10:49 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8593fe65-33ce-428b-8a1b-b350f7f66af3' | System | 26 Sep 2020 04:20:59 |
| User entered '1' | System | 26 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8593fe65-33ce-428b-8a1b-b350f7f66af3' | System | 26 Sep 2020 04:20:59 |
| User entered '0' | System | 26 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8593fe65-33ce-428b-8a1b-b350f7f66af3' | System | 26 Sep 2020 04:20:59 |
| User entered '25 Sep 2020 23:20' | System | 26 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 03:00:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 03:00:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 25 Sep 2020 03:32:16 |
| User entered 'Day 11' | System | 25 Sep 2020 03:32:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:27', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7cb987b5-96d4-4536-a6d7-b35b3b7a7573' | System | 27 Sep 2020 02:31:45 |
| User entered 'Yes (Y)' | System | 27 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7cb987b5-96d4-4536-a6d7-b35b3b7a7573' | System | 27 Sep 2020 02:31:45 |
| User entered '98.7' | System | 27 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7cb987b5-96d4-4536-a6d7-b35b3b7a7573' | System | 27 Sep 2020 02:31:45 |
| User entered 'Yes (Y)' | System | 27 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Acetaminophen for headache 1000 mg ' (Site from System). | | 04 Nov 2020 23:11:05 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 27 Sep 2020 02:31:45 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7cb987b5-96d4-4536-a6d7-b35b3b7a7573' | System | 27 Sep 2020 02:31:45 |
| User entered '1' | System | 27 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7cb987b5-96d4-4536-a6d7-b35b3b7a7573' | System | 27 Sep 2020 02:31:45 |
| User entered '0' | System | 27 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7cb987b5-96d4-4536-a6d7-b35b3b7a7573' | System | 27 Sep 2020 02:31:45 |
| User entered '26 Sep 2020 21:31' | System | 27 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Sep 2020 12:00' | System | 25 Sep 2020 03:32:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Sep 2020 11:59' | System | 25 Sep 2020 03:32:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 26 Sep 2020 04:20:59 |
| User entered 'Day 12' | System | 26 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9b1e9b18-810c-4f87-87ce-fe8ba5f13395' | System | 28 Sep 2020 04:52:43 |
| User entered 'Yes (Y)' | System | 28 Sep 2020 04:52:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9b1e9b18-810c-4f87-87ce-fe8ba5f13395' | System | 28 Sep 2020 04:52:43 |
| User entered '98.8' | System | 28 Sep 2020 04:52:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9b1e9b18-810c-4f87-87ce-fe8ba5f13395' | System | 28 Sep 2020 04:52:43 |
| User entered 'Yes (Y)' | System | 28 Sep 2020 04:52:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Acetaminophen for headache 1000 mg ' (Site from System). | | 04 Nov 2020 23:11:22 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 28 Sep 2020 04:52:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9b1e9b18-810c-4f87-87ce-fe8ba5f13395' | System | 28 Sep 2020 04:52:43 |
| User entered '1' | System | 28 Sep 2020 04:52:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9b1e9b18-810c-4f87-87ce-fe8ba5f13395' | System | 28 Sep 2020 04:52:43 |
| User entered '0' | System | 28 Sep 2020 04:52:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9b1e9b18-810c-4f87-87ce-fe8ba5f13395' | System | 28 Sep 2020 04:52:43 |
| User entered '27 Sep 2020 23:52' | System | 28 Sep 2020 04:52:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Sep 2020 12:00' | System | 26 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Sep 2020 11:59' | System | 26 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 27 Sep 2020 02:31:45 |
| User entered 'Day 13' | System | 27 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:15:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dda9ae64-fe90-43a3-8977-ce0b8e6729c4' | System | 29 Sep 2020 02:15:54 |
| User entered 'Yes (Y)' | System | 29 Sep 2020 02:15:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:15:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dda9ae64-fe90-43a3-8977-ce0b8e6729c4' | System | 29 Sep 2020 02:15:54 |
| User entered '98.9' | System | 29 Sep 2020 02:15:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:15:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dda9ae64-fe90-43a3-8977-ce0b8e6729c4' | System | 29 Sep 2020 02:15:54 |
| User entered 'Yes (Y)' | System | 29 Sep 2020 02:15:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Acetaminophen for headache 1000 mg ' (Site from System). | | 04 Nov 2020 23:11:36 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 29 Sep 2020 02:15:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:15:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dda9ae64-fe90-43a3-8977-ce0b8e6729c4' | System | 29 Sep 2020 02:15:54 |
| User entered '1' | System | 29 Sep 2020 02:15:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:15:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dda9ae64-fe90-43a3-8977-ce0b8e6729c4' | System | 29 Sep 2020 02:15:54 |
| User entered '0' | System | 29 Sep 2020 02:15:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:15:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dda9ae64-fe90-43a3-8977-ce0b8e6729c4' | System | 29 Sep 2020 02:15:54 |
| User entered '28 Sep 2020 21:15' | System | 29 Sep 2020 02:15:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Sep 2020 12:00' | System | 27 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Sep 2020 11:59' | System | 27 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 28 Sep 2020 04:52:43 |
| User entered 'Day 14' | System | 28 Sep 2020 04:52:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d09c252-2a5e-4ce1-b82f-a070d3356365' | System | 30 Sep 2020 03:18:52 |
| User entered 'Yes (Y)' | System | 30 Sep 2020 03:18:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d09c252-2a5e-4ce1-b82f-a070d3356365' | System | 30 Sep 2020 03:18:52 |
| User entered '98.9' | System | 30 Sep 2020 03:18:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d09c252-2a5e-4ce1-b82f-a070d3356365' | System | 30 Sep 2020 03:18:52 |
| User entered 'Yes (Y)' | System | 30 Sep 2020 03:18:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Acetaminophen for headache 1000 mg ' (Site from System). | | 04 Nov 2020 23:12:36 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 30 Sep 2020 03:18:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d09c252-2a5e-4ce1-b82f-a070d3356365' | System | 30 Sep 2020 03:18:52 |
| User entered '1' | System | 30 Sep 2020 03:18:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d09c252-2a5e-4ce1-b82f-a070d3356365' | System | 30 Sep 2020 03:18:52 |
| User entered '0' | System | 30 Sep 2020 03:18:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d09c252-2a5e-4ce1-b82f-a070d3356365' | System | 30 Sep 2020 03:18:52 |
| User entered '29 Sep 2020 22:18' | System | 30 Sep 2020 03:18:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 04:52:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 04:52:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 29 Sep 2020 02:15:54 |
| User entered 'Day 15' | System | 29 Sep 2020 02:15:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:21:09

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b758bcb3-e86c-40c7-9507-eb8903ea8104' | System | 01 Oct 2020 01:03:52 |
| User entered 'Yes (Y)' | System | 01 Oct 2020 01:03:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b758bcb3-e86c-40c7-9507-eb8903ea8104' | System | 01 Oct 2020 01:03:52 |
| User entered '98.7' | System | 01 Oct 2020 01:03:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b758bcb3-e86c-40c7-9507-eb8903ea8104' | System | 01 Oct 2020 01:03:52 |
| User entered 'Yes (Y)' | System | 01 Oct 2020 01:03:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:21:09

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Acetaminophen for headache 1000 mg ' (Site from System). | | 04 Nov 2020 23:12:53 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 01 Oct 2020 01:03:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b758bcb3-e86c-40c7-9507-eb8903ea8104' | System | 01 Oct 2020 01:03:52 |
| User entered '1' | System | 01 Oct 2020 01:03:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:21:09

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b758bcb3-e86c-40c7-9507-eb8903ea8104' | System | 01 Oct 2020 01:03:52 |
| User entered '0' | System | 01 Oct 2020 01:03:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b758bcb3-e86c-40c7-9507-eb8903ea8104' | System | 01 Oct 2020 01:03:52 |
| User entered '30 Sep 2020 20:03' | System | 01 Oct 2020 01:03:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Sep 2020 12:00' | System | 29 Sep 2020 02:15:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '01 Oct 2020 11:59' | System | 29 Sep 2020 02:15:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 30 Sep 2020 03:18:52 |
| User entered 'Day 16' | System | 30 Sep 2020 03:18:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:21:09

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c2e0b712-884a-4078-87dc-3aeba9c9a25b' | System | 02 Oct 2020 03:27:36 |
| User entered 'Yes (Y)' | System | 02 Oct 2020 03:27:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:21:09

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:29', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c2e0b712-884a-4078-87dc-3aeba9c9a25b' | System | 02 Oct 2020 03:27:36 |
| User entered '98.6' | System | 02 Oct 2020 03:27:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:21:09

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c2e0b712-884a-4078-87dc-3aeba9c9a25b' | System | 02 Oct 2020 03:27:36 |
| User entered 'No (N)' | System | 02 Oct 2020 03:27:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c2e0b712-884a-4078-87dc-3aeba9c9a25b' | System | 02 Oct 2020 03:27:36 |
| User entered '01 Oct 2020 22:27' | System | 02 Oct 2020 03:27:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '01 Oct 2020 12:00' | System | 30 Sep 2020 03:18:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '02 Oct 2020 11:59' | System | 30 Sep 2020 03:18:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f7286483-2821-4d61-8999-ec33ff84bd28' | System | 16 Sep 2020 18:05:30 |
| User entered 'None (1)' | System | 16 Sep 2020 18:05:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f7286483-2821-4d61-8999-ec33ff84bd28' | System | 16 Sep 2020 18:05:30 |
| User entered 'No (N)' | System | 16 Sep 2020 18:05:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f7286483-2821-4d61-8999-ec33ff84bd28' | System | 16 Sep 2020 18:05:30 |
| User entered 'No (N)' | System | 16 Sep 2020 18:05:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f7286483-2821-4d61-8999-ec33ff84bd28' | System | 16 Sep 2020 18:05:30 |
| User entered 'None (1)' | System | 16 Sep 2020 18:05:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f7286483-2821-4d61-8999-ec33ff84bd28' | System | 16 Sep 2020 18:05:30 |
| User entered '16 Sep 2020 13:05' | System | 16 Sep 2020 18:05:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Sep 2020 12:26' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Sep 2020 14:56' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 1, after vaccination (at home)' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:48:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '27a59b0a-6bd8-44c2-a9f1-bef295d3319f' | System | 17 Sep 2020 02:49:10 |
| User entered 'None (1)' | System | 17 Sep 2020 02:49:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:48:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '27a59b0a-6bd8-44c2-a9f1-bef295d3319f' | System | 17 Sep 2020 02:49:10 |
| User entered 'No (N)' | System | 17 Sep 2020 02:49:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Is there any any SWELLING/HARDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '27a59b0a-6bd8-44c2-a9f1-bef295d3319f' | System | 17 Sep 2020 02:49:10 |
| User entered 'No (N)' | System | 17 Sep 2020 02:49:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '27a59b0a-6bd8-44c2-a9f1-bef295d3319f' | System | 17 Sep 2020 02:49:10 |
| User entered 'None (1)' | System | 17 Sep 2020 02:49:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '27a59b0a-6bd8-44c2-a9f1-bef295d3319f' | System | 17 Sep 2020 02:49:10 |
| User entered '16 Sep 2020 21:49' | System | 17 Sep 2020 02:49:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Sep 2020 15:51' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '17 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 2' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ed496555-c58c-4fb7-a327-5f986c678256' | System | 18 Sep 2020 02:25:15 |
| User entered 'Does not interfere with activity (2)' | System | 18 Sep 2020 02:25:15 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ed496555-c58c-4fb7-a327-5f986c678256' | System | 18 Sep 2020 02:25:15 |
| User entered 'No (N)' | System | 18 Sep 2020 02:25:15 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ed496555-c58c-4fb7-a327-5f986c678256' | System | 18 Sep 2020 02:25:15 |
| User entered 'No (N)' | System | 18 Sep 2020 02:25:15 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ed496555-c58c-4fb7-a327-5f986c678256' | System | 18 Sep 2020 02:25:15 |
| User entered 'None (1)' | System | 18 Sep 2020 02:25:15 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ed496555-c58c-4fb7-a327-5f986c678256' | System | 18 Sep 2020 02:25:15 |
| User entered '17 Sep 2020 21:25' | System | 18 Sep 2020 02:25:15 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '17 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '18 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 3' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e8a8af3-41db-40c7-8c8f-05683fc265aa' | System | 19 Sep 2020 04:39:26 |
| User entered 'Does not interfere with activity (2)' | System | 19 Sep 2020 04:39:26 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e8a8af3-41db-40c7-8c8f-05683fc265aa' | System | 19 Sep 2020 04:39:26 |
| User entered 'No (N)' | System | 19 Sep 2020 04:39:26 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e8a8af3-41db-40c7-8c8f-05683fc265aa' | System | 19 Sep 2020 04:39:26 |
| User entered 'No (N)' | System | 19 Sep 2020 04:39:26 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e8a8af3-41db-40c7-8c8f-05683fc265aa' | System | 19 Sep 2020 04:39:26 |
| User entered 'None (1)' | System | 19 Sep 2020 04:39:26 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e8a8af3-41db-40c7-8c8f-05683fc265aa' | System | 19 Sep 2020 04:39:26 |
| User entered '18 Sep 2020 23:39' | System | 19 Sep 2020 04:39:26 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 4' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:48:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bd822b16-960e-4411-a2cf-e73a56a10a0b' | System | 20 Sep 2020 02:49:10 |
| User entered 'Does not interfere with activity (2)' | System | 20 Sep 2020 02:49:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:48:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bd822b16-960e-4411-a2cf-e73a56a10a0b' | System | 20 Sep 2020 02:49:10 |
| User entered 'No (N)' | System | 20 Sep 2020 02:49:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bd822b16-960e-4411-a2cf-e73a56a10a0b' | System | 20 Sep 2020 02:49:10 |
| User entered 'No (N)' | System | 20 Sep 2020 02:49:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bd822b16-960e-4411-a2cf-e73a56a10a0b' | System | 20 Sep 2020 02:49:10 |
| User entered 'None (1)' | System | 20 Sep 2020 02:49:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bd822b16-960e-4411-a2cf-e73a56a10a0b' | System | 20 Sep 2020 02:49:10 |
| User entered '19 Sep 2020 21:49' | System | 20 Sep 2020 02:49:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '19 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '20 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 5' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9c27126-18a7-4ad7-ac1a-6c543e5f56b2' | System | 21 Sep 2020 04:58:44 |
| User entered 'None (1)' | System | 21 Sep 2020 04:58:44 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:35', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9c27126-18a7-4ad7-ac1a-6c543e5f56b2' | System | 21 Sep 2020 04:58:44 |
| User entered 'No (N)' | System | 21 Sep 2020 04:58:44 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9c27126-18a7-4ad7-ac1a-6c543e5f56b2' | System | 21 Sep 2020 04:58:44 |
| User entered 'No (N)' | System | 21 Sep 2020 04:58:44 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9c27126-18a7-4ad7-ac1a-6c543e5f56b2' | System | 21 Sep 2020 04:58:44 |
| User entered 'None (1)' | System | 21 Sep 2020 04:58:44 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9c27126-18a7-4ad7-ac1a-6c543e5f56b2' | System | 21 Sep 2020 04:58:44 |
| User entered '20 Sep 2020 23:58' | System | 21 Sep 2020 04:58:44 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '20 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '21 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 6' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25f95f86-69dd-4093-9599-492c506ddb84' | System | 22 Sep 2020 02:32:10 |
| User entered 'None (1)' | System | 22 Sep 2020 02:32:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25f95f86-69dd-4093-9599-492c506ddb84' | System | 22 Sep 2020 02:32:10 |
| User entered 'No (N)' | System | 22 Sep 2020 02:32:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25f95f86-69dd-4093-9599-492c506ddb84' | System | 22 Sep 2020 02:32:10 |
| User entered 'No (N)' | System | 22 Sep 2020 02:32:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25f95f86-69dd-4093-9599-492c506ddb84' | System | 22 Sep 2020 02:32:10 |
| User entered 'None (1)' | System | 22 Sep 2020 02:32:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25f95f86-69dd-4093-9599-492c506ddb84' | System | 22 Sep 2020 02:32:10 |
| User entered '21 Sep 2020 21:32' | System | 22 Sep 2020 02:32:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '21 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '22 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 7' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3fe76b85-1f30-4669-8f83-4b42e49b8416' | System | 23 Sep 2020 04:20:22 |
| User entered 'None (1)' | System | 23 Sep 2020 04:20:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3fe76b85-1f30-4669-8f83-4b42e49b8416' | System | 23 Sep 2020 04:20:22 |
| User entered 'No (N)' | System | 23 Sep 2020 04:20:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3fe76b85-1f30-4669-8f83-4b42e49b8416' | System | 23 Sep 2020 04:20:22 |
| User entered 'No (N)' | System | 23 Sep 2020 04:20:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3fe76b85-1f30-4669-8f83-4b42e49b8416' | System | 23 Sep 2020 04:20:22 |
| User entered 'None (1)' | System | 23 Sep 2020 04:20:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:18', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3fe76b85-1f30-4669-8f83-4b42e49b8416' | System | 23 Sep 2020 04:20:22 |
| User entered '22 Sep 2020 23:20' | System | 23 Sep 2020 04:20:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '22 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32' | System | 16 Sep 2020 18:05:54 |
| User entered 'None (0)' | System | 16 Sep 2020 18:05:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32' | System | 16 Sep 2020 18:05:54 |
| User entered 'None (0)' | System | 16 Sep 2020 18:05:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32' | System | 16 Sep 2020 18:05:54 |
| User entered 'None (0)' | System | 16 Sep 2020 18:05:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32' | System | 16 Sep 2020 18:05:54 |
| User entered 'None (0)' | System | 16 Sep 2020 18:05:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32' | System | 16 Sep 2020 18:05:54 |
| User entered 'None (0)' | System | 16 Sep 2020 18:05:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32' | System | 16 Sep 2020 18:05:54 |
| User entered 'None (0)' | System | 16 Sep 2020 18:05:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32' | System | 16 Sep 2020 18:05:54 |
| User entered 'No (N)' | System | 16 Sep 2020 18:05:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32' | System | 16 Sep 2020 18:05:54 |
| User entered '16 Sep 2020 13:05' | System | 16 Sep 2020 18:05:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Sep 2020 12:26' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Sep 2020 14:56' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 1, after vaccination (at home)' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4' | System | 17 Sep 2020 02:49:36 |
| User entered 'No interference with activity (1)' | System | 17 Sep 2020 02:49:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4' | System | 17 Sep 2020 02:49:36 |
| User entered 'No interference with activity (1)' | System | 17 Sep 2020 02:49:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4' | System | 17 Sep 2020 02:49:36 |
| User entered 'None (0)' | System | 17 Sep 2020 02:49:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4' | System | 17 Sep 2020 02:49:36 |
| User entered 'None (0)' | System | 17 Sep 2020 02:49:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4' | System | 17 Sep 2020 02:49:36 |
| User entered 'None (0)' | System | 17 Sep 2020 02:49:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4' | System | 17 Sep 2020 02:49:36 |
| User entered 'None (0)' | System | 17 Sep 2020 02:49:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:29', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4' | System | 17 Sep 2020 02:49:36 |
| User entered 'No (N)' | System | 17 Sep 2020 02:49:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4' | System | 17 Sep 2020 02:49:36 |
| User entered '16 Sep 2020 21:49' | System | 17 Sep 2020 02:49:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '16 Sep 2020 15:51' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '17 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 2' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327' | System | 18 Sep 2020 02:25:48 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 18 Sep 2020 02:25:48 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327' | System | 18 Sep 2020 02:25:48 |
| User entered 'No interference with activity (1)' | System | 18 Sep 2020 02:25:48 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327' | System | 18 Sep 2020 02:25:48 |
| User entered 'Some interference with activity (2)' | System | 18 Sep 2020 02:25:48 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327' | System | 18 Sep 2020 02:25:48 |
| User entered 'Some interference with activity (2)' | System | 18 Sep 2020 02:25:48 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327' | System | 18 Sep 2020 02:25:48 |
| User entered 'None (0)' | System | 18 Sep 2020 02:25:48 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327' | System | 18 Sep 2020 02:25:48 |
| User entered 'None (0)' | System | 18 Sep 2020 02:25:48 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327' | System | 18 Sep 2020 02:25:48 |
| User entered 'No (N)' | System | 18 Sep 2020 02:25:48 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327' | System | 18 Sep 2020 02:25:48 |
| User entered '17 Sep 2020 21:25' | System | 18 Sep 2020 02:25:48 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '17 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '18 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 3' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853' | System | 19 Sep 2020 04:39:59 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 19 Sep 2020 04:39:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:35', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853' | System | 19 Sep 2020 04:39:59 |
| User entered 'Some interference with activity (2)' | System | 19 Sep 2020 04:39:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853' | System | 19 Sep 2020 04:39:59 |
| User entered 'No interference with activity (1)' | System | 19 Sep 2020 04:39:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853' | System | 19 Sep 2020 04:39:59 |
| User entered 'No interference with activity (1)' | System | 19 Sep 2020 04:39:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853' | System | 19 Sep 2020 04:39:59 |
| User entered 'None (0)' | System | 19 Sep 2020 04:39:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853' | System | 19 Sep 2020 04:39:59 |
| User entered 'None (0)' | System | 19 Sep 2020 04:39:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853' | System | 19 Sep 2020 04:39:59 |
| User entered 'No (N)' | System | 19 Sep 2020 04:39:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853' | System | 19 Sep 2020 04:39:59 |
| User entered '18 Sep 2020 23:39' | System | 19 Sep 2020 04:39:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 4' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53' | System | 20 Sep 2020 02:50:01 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 20 Sep 2020 02:50:01 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53' | System | 20 Sep 2020 02:50:01 |
| User entered 'No interference with activity (1)' | System | 20 Sep 2020 02:50:01 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53' | System | 20 Sep 2020 02:50:01 |
| User entered 'None (0)' | System | 20 Sep 2020 02:50:01 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53' | System | 20 Sep 2020 02:50:01 |
| User entered 'No interference with activity (1)' | System | 20 Sep 2020 02:50:01 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53' | System | 20 Sep 2020 02:50:01 |
| User entered 'None (0)' | System | 20 Sep 2020 02:50:01 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53' | System | 20 Sep 2020 02:50:01 |
| User entered 'None (0)' | System | 20 Sep 2020 02:50:01 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53' | System | 20 Sep 2020 02:50:01 |
| User entered 'No (N)' | System | 20 Sep 2020 02:50:01 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53' | System | 20 Sep 2020 02:50:01 |
| User entered '19 Sep 2020 21:49' | System | 20 Sep 2020 02:50:01 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '19 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '20 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 5' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119' | System | 21 Sep 2020 04:59:14 |
| User entered 'No interference with activity (1)' | System | 21 Sep 2020 04:59:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119' | System | 21 Sep 2020 04:59:14 |
| User entered 'No interference with activity (1)' | System | 21 Sep 2020 04:59:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:58', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119' | System | 21 Sep 2020 04:59:14 |
| User entered 'No interference with activity (1)' | System | 21 Sep 2020 04:59:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:59:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119' User entered 'None (0)' | System | 21 Sep 2020 04:59:14 |
| | System | 21 Sep 2020 04:59:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:59:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119' | System | 21 Sep 2020 04:59:14 |
| User entered 'None (0)' | System | 21 Sep 2020 04:59:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:59:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119' | System | 21 Sep 2020 04:59:14 |
| User entered 'None (0)' | System | 21 Sep 2020 04:59:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:59:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119' | System | 21 Sep 2020 04:59:14 |
| User entered 'No (N)' | System | 21 Sep 2020 04:59:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:59:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119' | System | 21 Sep 2020 04:59:14 |
| User entered '20 Sep 2020 23:59' | System | 21 Sep 2020 04:59:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '20 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '21 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 6' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8' | System | 22 Sep 2020 02:32:30 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8' | System | 22 Sep 2020 02:32:30 |
| User entered 'Some interference with activity (2)' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8' | System | 22 Sep 2020 02:32:30 |
| User entered 'No interference with activity (1)' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8' | System | 22 Sep 2020 02:32:30 |
| User entered 'None (0)' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8' | System | 22 Sep 2020 02:32:30 |
| User entered 'None (0)' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8' | System | 22 Sep 2020 02:32:30 |
| User entered 'None (0)' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8' | System | 22 Sep 2020 02:32:30 |
| User entered 'No (N)' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8' | System | 22 Sep 2020 02:32:30 |
| User entered '21 Sep 2020 21:32' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '21 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '22 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 16 Sep 2020 17:06:49 |
| User entered 'Day 7' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b' | System | 23 Sep 2020 04:20:59 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b' | System | 23 Sep 2020 04:20:59 |
| User entered 'Some interference with activity (2)' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b' | System | 23 Sep 2020 04:20:59 |
| User entered 'Some interference with activity (2)' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b' | System | 23 Sep 2020 04:20:59 |
| User entered 'Some interference with activity (2)' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:47', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b' | System | 23 Sep 2020 04:20:59 |
| User entered 'None (0)' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b' | System | 23 Sep 2020 04:20:59 |
| User entered 'None (0)' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b' | System | 23 Sep 2020 04:20:59 |
| User entered 'No (N)' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b' | System | 23 Sep 2020 04:20:59 |
| User entered '22 Sep 2020 23:20' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '22 Sep 2020 12:00' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Sep 2020 11:59' | System | 16 Sep 2020 17:06:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 22 Sep 2020 02:32:30 |
| User entered 'Day 8' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dced4acd-204f-464f-8a46-27cd90a52551' | System | 24 Sep 2020 03:00:26 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 24 Sep 2020 03:00:26 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dced4acd-204f-464f-8a46-27cd90a52551' | System | 24 Sep 2020 03:00:26 |
| User entered '23 Sep 2020 22:00' | System | 24 Sep 2020 03:00:26 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 23 Sep 2020 04:20:59 |
| User entered 'Day 9' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '60cf7f2c-3c3a-4da4-aae0-83683a411a06' | System | 25 Sep 2020 03:32:27 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 25 Sep 2020 03:32:27 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '60cf7f2c-3c3a-4da4-aae0-83683a411a06' | System | 25 Sep 2020 03:32:27 |
| User entered '24 Sep 2020 22:32' | System | 25 Sep 2020 03:32:27 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Sep 2020 12:00' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Sep 2020 11:59' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 24 Sep 2020 03:00:26 |
| User entered 'Day 10' | System | 24 Sep 2020 03:00:26 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'fb540251-cceb-4241-93bb-9f4224faec5c' | System | 26 Sep 2020 04:21:08 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 26 Sep 2020 04:21:08 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'fb540251-cceb-4241-93bb-9f4224faec5c' | System | 26 Sep 2020 04:21:08 |
| User entered '25 Sep 2020 23:21' | System | 26 Sep 2020 04:21:08 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 03:00:26 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 03:00:26 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 25 Sep 2020 03:32:27 |
| User entered 'Day 11' | System | 25 Sep 2020 03:32:27 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0d7e604d-2485-4696-9fa7-0168e2c91a25' | System | 27 Sep 2020 02:31:53 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 27 Sep 2020 02:31:53 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0d7e604d-2485-4696-9fa7-0168e2c91a25' | System | 27 Sep 2020 02:31:53 |
| User entered '26 Sep 2020 21:31' | System | 27 Sep 2020 02:31:53 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Sep 2020 12:00' | System | 25 Sep 2020 03:32:27 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Sep 2020 11:59' | System | 25 Sep 2020 03:32:27 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 26 Sep 2020 04:21:08 |
| User entered 'Day 12' | System | 26 Sep 2020 04:21:08 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:47', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '02ecafb3-026d-42d3-a808-e320d3a16658' | System | 28 Sep 2020 04:52:53 |
| User entered 'No interference with activity (1)' | System | 28 Sep 2020 04:52:53 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '02ecafb3-026d-42d3-a808-e320d3a16658' | System | 28 Sep 2020 04:52:53 |
| User entered '27 Sep 2020 23:52' | System | 28 Sep 2020 04:52:53 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Sep 2020 12:00' | System | 26 Sep 2020 04:21:08 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Sep 2020 11:59' | System | 26 Sep 2020 04:21:08 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 27 Sep 2020 02:31:53 |
| User entered 'Day 13' | System | 27 Sep 2020 02:31:53 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8edffc00-aa75-48f7-bbc4-e07db11c98dd' | System | 29 Sep 2020 02:16:16 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 29 Sep 2020 02:16:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8edffc00-aa75-48f7-bbc4-e07db11c98dd' | System | 29 Sep 2020 02:16:16 |
| User entered '28 Sep 2020 21:16' | System | 29 Sep 2020 02:16:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Sep 2020 12:00' | System | 27 Sep 2020 02:31:53 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Sep 2020 11:59' | System | 27 Sep 2020 02:31:53 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 28 Sep 2020 04:52:53 |
| User entered 'Day 14' | System | 28 Sep 2020 04:52:53 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7a06c8c0-6163-4953-916a-a070a9737bfc' | System | 30 Sep 2020 03:19:03 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 30 Sep 2020 03:19:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7a06c8c0-6163-4953-916a-a070a9737bfc' | System | 30 Sep 2020 03:19:03 |
| User entered '29 Sep 2020 22:18' | System | 30 Sep 2020 03:19:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 04:52:53 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 04:52:53 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 29 Sep 2020 02:16:16 |
| User entered 'Day 15' | System | 29 Sep 2020 02:16:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4a6d0a1-4f28-48d2-943c-40f944bae002' | System | 01 Oct 2020 01:03:59 |
| User entered 'No interference with activity (1)' | System | 01 Oct 2020 01:03:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4a6d0a1-4f28-48d2-943c-40f944bae002' | System | 01 Oct 2020 01:03:59 |
| User entered '30 Sep 2020 20:03' | System | 01 Oct 2020 01:03:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Sep 2020 12:00' | System | 29 Sep 2020 02:16:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '01 Oct 2020 11:59' | System | 29 Sep 2020 02:16:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 30 Sep 2020 03:19:03 |
| User entered 'Day 16' | System | 30 Sep 2020 03:19:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0f44b9d3-f1b1-40fb-bebb-6d88c3733119' | System | 02 Oct 2020 03:27:45 |
| User entered 'No interference with activity (1)' | System | 02 Oct 2020 03:27:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0f44b9d3-f1b1-40fb-bebb-6d88c3733119' | System | 02 Oct 2020 03:27:45 |
| User entered '01 Oct 2020 22:27' | System | 02 Oct 2020 03:27:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '01 Oct 2020 12:00' | System | 30 Sep 2020 03:19:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '02 Oct 2020 11:59' | System | 30 Sep 2020 03:19:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 01 Oct 2020 01:03:59 |
| User entered 'Day 17' | System | 01 Oct 2020 01:03:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '02 Oct 2020 12:00' | System | 01 Oct 2020 01:03:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '03 Oct 2020 11:59' | System | 01 Oct 2020 01:03:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(18)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 02 Oct 2020 03:27:45 |
| User entered 'Day 18' | System | 02 Oct 2020 03:27:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(18)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:22:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e2d0a044-6306-4613-81e9-4e653680f723' | System | 04 Oct 2020 03:22:52 |
| User entered 'No interference with activity (1)' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:22:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e2d0a044-6306-4613-81e9-4e653680f723' | System | 04 Oct 2020 03:22:52 |
| User entered '03 Oct 2020 22:22' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '03 Oct 2020 12:00' | System | 02 Oct 2020 03:27:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '04 Oct 2020 11:59' | System | 02 Oct 2020 03:27:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(19)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 04 Oct 2020 03:22:52 |
| User entered 'Day 19' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(19)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:46:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '17bc4894-08ea-4bc1-8d17-eba0779377ba' | System | 05 Oct 2020 04:46:45 |
| User entered 'No interference with activity (1)' | System | 05 Oct 2020 04:46:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:46:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '17bc4894-08ea-4bc1-8d17-eba0779377ba' | System | 05 Oct 2020 04:46:45 |
| User entered '04 Oct 2020 23:46' | System | 05 Oct 2020 04:46:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '04 Oct 2020 12:00' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '05 Oct 2020 11:59' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(20)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 04 Oct 2020 03:22:52 |
| User entered 'Day 20' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(20)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '05 Oct 2020 12:00' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '06 Oct 2020 11:59' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(21)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 05 Oct 2020 04:46:45 |
| User entered 'Day 21' | System | 05 Oct 2020 04:46:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(21)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c03ac26-88c5-44c8-9148-b6ef22437a23' | System | 07 Oct 2020 05:07:09 |
| User entered 'None (0)' | System | 07 Oct 2020 05:07:09 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c03ac26-88c5-44c8-9148-b6ef22437a23' | System | 07 Oct 2020 05:07:09 |
| User entered '07 Oct 2020 00:07' | System | 07 Oct 2020 05:07:09 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '06 Oct 2020 12:00' | System | 05 Oct 2020 04:46:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Headache_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '07 Oct 2020 11:59' | System | 05 Oct 2020 04:46:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 22 Sep 2020 02:32:30 |
| User entered 'Day 8' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bb552811-a7e7-4479-99a1-8ba83d9bb8e2' | System | 24 Sep 2020 03:00:27 |
| User entered 'No interference with activity (1)' | System | 24 Sep 2020 03:00:27 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bb552811-a7e7-4479-99a1-8ba83d9bb8e2' | System | 24 Sep 2020 03:00:27 |
| User entered '23 Sep 2020 22:00' | System | 24 Sep 2020 03:00:27 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 23 Sep 2020 04:20:59 |
| User entered 'Day 9' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a6a13a2b-76d2-43a1-9f55-e714b8c5e121' | System | 25 Sep 2020 03:32:36 |
| User entered 'Some interference with activity (2)' | System | 25 Sep 2020 03:32:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a6a13a2b-76d2-43a1-9f55-e714b8c5e121' | System | 25 Sep 2020 03:32:36 |
| User entered '24 Sep 2020 22:32' | System | 25 Sep 2020 03:32:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Sep 2020 12:00' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Sep 2020 11:59' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 24 Sep 2020 03:00:27 |
| User entered 'Day 10' | System | 24 Sep 2020 03:00:27 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ca62fd2e-541e-49c7-b928-98059e238122' | System | 26 Sep 2020 04:21:10 |
| User entered 'Some interference with activity (2)' | System | 26 Sep 2020 04:21:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ca62fd2e-541e-49c7-b928-98059e238122' | System | 26 Sep 2020 04:21:10 |
| User entered '25 Sep 2020 23:21' | System | 26 Sep 2020 04:21:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 03:00:27 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 03:00:27 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 25 Sep 2020 03:32:36 |
| User entered 'Day 11' | System | 25 Sep 2020 03:32:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:32:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c43beeee-79a7-4fc4-bbee-8378f8ac8029' | System | 27 Sep 2020 02:32:06 |
| User entered 'No interference with activity (1)' | System | 27 Sep 2020 02:32:06 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:32:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c43beeee-79a7-4fc4-bbee-8378f8ac8029' | System | 27 Sep 2020 02:32:06 |
| User entered '26 Sep 2020 21:32' | System | 27 Sep 2020 02:32:06 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Sep 2020 12:00' | System | 25 Sep 2020 03:32:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Sep 2020 11:59' | System | 25 Sep 2020 03:32:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 26 Sep 2020 04:21:10 |
| User entered 'Day 12' | System | 26 Sep 2020 04:21:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '773367c0-503c-4641-a893-c0c8dcd0cb97' | System | 28 Sep 2020 04:53:00 |
| User entered 'Some interference with activity (2)' | System | 28 Sep 2020 04:53:00 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '773367c0-503c-4641-a893-c0c8dcd0cb97' | System | 28 Sep 2020 04:53:00 |
| User entered '27 Sep 2020 23:52' | System | 28 Sep 2020 04:53:00 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Sep 2020 12:00' | System | 26 Sep 2020 04:21:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Sep 2020 11:59' | System | 26 Sep 2020 04:21:10 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 27 Sep 2020 02:32:06 |
| User entered 'Day 13' | System | 27 Sep 2020 02:32:06 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dc1c60c7-a86b-433d-8e59-59c54886c8ef' | System | 29 Sep 2020 02:16:21 |
| User entered 'Some interference with activity (2)' | System | 29 Sep 2020 02:16:21 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dc1c60c7-a86b-433d-8e59-59c54886c8ef' | System | 29 Sep 2020 02:16:21 |
| User entered '28 Sep 2020 21:16' | System | 29 Sep 2020 02:16:21 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Sep 2020 12:00' | System | 27 Sep 2020 02:32:06 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Sep 2020 11:59' | System | 27 Sep 2020 02:32:06 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 28 Sep 2020 04:53:00 |
| User entered 'Day 14' | System | 28 Sep 2020 04:53:00 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:19:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '79b8b5f8-64a5-425f-9d27-ab830530b179' | System | 30 Sep 2020 03:19:08 |
| User entered 'No interference with activity (1)' | System | 30 Sep 2020 03:19:08 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:19:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '79b8b5f8-64a5-425f-9d27-ab830530b179' | System | 30 Sep 2020 03:19:08 |
| User entered '29 Sep 2020 22:19' | System | 30 Sep 2020 03:19:08 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 04:53:00 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 04:53:00 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 29 Sep 2020 02:16:21 |
| User entered 'Day 15' | System | 29 Sep 2020 02:16:21 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:04:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a0564e18-9752-40a5-8849-ca47cb0dbcd3' | System | 01 Oct 2020 01:04:09 |
| User entered 'No interference with activity (1)' | System | 01 Oct 2020 01:04:09 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:04:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a0564e18-9752-40a5-8849-ca47cb0dbcd3' | System | 01 Oct 2020 01:04:09 |
| User entered '30 Sep 2020 20:04' | System | 01 Oct 2020 01:04:09 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Sep 2020 12:00' | System | 29 Sep 2020 02:16:21 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '01 Oct 2020 11:59' | System | 29 Sep 2020 02:16:21 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 30 Sep 2020 03:19:08 |
| User entered 'Day 16' | System | 30 Sep 2020 03:19:08 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '18584f19-6eb2-4dcf-ab56-3a307c8fad24' | System | 02 Oct 2020 03:27:52 |
| User entered 'No interference with activity (1)' | System | 02 Oct 2020 03:27:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '18584f19-6eb2-4dcf-ab56-3a307c8fad24' | System | 02 Oct 2020 03:27:52 |
| User entered '01 Oct 2020 22:27' | System | 02 Oct 2020 03:27:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '01 Oct 2020 12:00' | System | 30 Sep 2020 03:19:08 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '02 Oct 2020 11:59' | System | 30 Sep 2020 03:19:08 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 01 Oct 2020 01:04:09 |
| User entered 'Day 17' | System | 01 Oct 2020 01:04:09 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '02 Oct 2020 12:00' | System | 01 Oct 2020 01:04:09 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '03 Oct 2020 11:59' | System | 01 Oct 2020 01:04:09 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 02 Oct 2020 03:27:52 |
| User entered 'Day 18' | System | 02 Oct 2020 03:27:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:22:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '276290a8-6f97-4edb-bfe8-6d2381e62daa' | System | 04 Oct 2020 03:22:58 |
| User entered 'No interference with activity (1)' | System | 04 Oct 2020 03:22:58 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:22:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '276290a8-6f97-4edb-bfe8-6d2381e62daa' | System | 04 Oct 2020 03:22:58 |
| User entered '03 Oct 2020 22:22' | System | 04 Oct 2020 03:22:58 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '03 Oct 2020 12:00' | System | 02 Oct 2020 03:27:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '04 Oct 2020 11:59' | System | 02 Oct 2020 03:27:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 04 Oct 2020 03:22:58 |
| User entered 'Day 19' | System | 04 Oct 2020 03:22:58 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:46:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b86f0d49-dae0-41b8-80d4-8a706729a6dc' | System | 05 Oct 2020 04:46:52 |
| User entered 'No interference with activity (1)' | System | 05 Oct 2020 04:46:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:46:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b86f0d49-dae0-41b8-80d4-8a706729a6dc' | System | 05 Oct 2020 04:46:52 |
| User entered '04 Oct 2020 23:46' | System | 05 Oct 2020 04:46:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '04 Oct 2020 12:00' | System | 04 Oct 2020 03:22:58 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '05 Oct 2020 11:59' | System | 04 Oct 2020 03:22:58 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 04 Oct 2020 03:22:58 |
| User entered 'Day 20' | System | 04 Oct 2020 03:22:58 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '05 Oct 2020 12:00' | System | 04 Oct 2020 03:22:58 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '06 Oct 2020 11:59' | System | 04 Oct 2020 03:22:58 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 05 Oct 2020 04:46:52 |
| User entered 'Day 21' | System | 05 Oct 2020 04:46:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5fe062c8-a2e2-4de4-9476-14f8930ecc57' | System | 07 Oct 2020 05:07:16 |
| User entered 'No interference with activity (1)' | System | 07 Oct 2020 05:07:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5fe062c8-a2e2-4de4-9476-14f8930ecc57' | System | 07 Oct 2020 05:07:16 |
| User entered '07 Oct 2020 00:07' | System | 07 Oct 2020 05:07:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '06 Oct 2020 12:00' | System | 05 Oct 2020 04:46:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '07 Oct 2020 11:59' | System | 05 Oct 2020 04:46:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 07 Oct 2020 05:07:16 |
| User entered 'Day 22' | System | 07 Oct 2020 05:07:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T21:04:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2ca2eaba-f02d-4d96-a948-da14008a6d73' | System | 08 Oct 2020 02:04:13 |
| User entered 'Some interference with activity (2)' | System | 08 Oct 2020 02:04:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T21:04:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2ca2eaba-f02d-4d96-a948-da14008a6d73' | System | 08 Oct 2020 02:04:13 |
| User entered '07 Oct 2020 21:04' | System | 08 Oct 2020 02:04:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '07 Oct 2020 12:00' | System | 07 Oct 2020 05:07:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '08 Oct 2020 11:59' | System | 07 Oct 2020 05:07:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 07 Oct 2020 05:07:16 |
| User entered 'Day 23' | System | 07 Oct 2020 05:07:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '08 Oct 2020 12:00' | System | 07 Oct 2020 05:07:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '09 Oct 2020 11:59' | System | 07 Oct 2020 05:07:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 08 Oct 2020 02:04:13 |
| User entered 'Day 24' | System | 08 Oct 2020 02:04:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-09T22:02:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0e36d7ce-aec9-46e9-87d9-f9e1f0f62988' | System | 10 Oct 2020 03:02:22 |
| User entered 'No interference with activity (1)' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-09T22:02:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0e36d7ce-aec9-46e9-87d9-f9e1f0f62988' | System | 10 Oct 2020 03:02:22 |
| User entered '09 Oct 2020 22:02' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '09 Oct 2020 12:00' | System | 08 Oct 2020 02:04:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '10 Oct 2020 11:59' | System | 08 Oct 2020 02:04:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 10 Oct 2020 03:02:22 |
| User entered 'Day 25' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-10T22:53:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a4e8cd96-6891-4fb9-9950-64bf08b36b45' | System | 11 Oct 2020 03:53:56 |
| User entered 'No interference with activity (1)' | System | 11 Oct 2020 03:53:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-10T22:53:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a4e8cd96-6891-4fb9-9950-64bf08b36b45' | System | 11 Oct 2020 03:53:56 |
| User entered '10 Oct 2020 22:53' | System | 11 Oct 2020 03:53:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '10 Oct 2020 12:00' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '11 Oct 2020 11:59' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 10 Oct 2020 03:02:22 |
| User entered 'Day 26' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-12T00:04:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '10333b44-ecc3-4281-b27e-efd21c18ca1d' | System | 12 Oct 2020 05:04:07 |
| User entered 'No interference with activity (1)' | System | 12 Oct 2020 05:04:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-12T00:04:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '10333b44-ecc3-4281-b27e-efd21c18ca1d' | System | 12 Oct 2020 05:04:07 |
| User entered '12 Oct 2020 00:04' | System | 12 Oct 2020 05:04:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '11 Oct 2020 12:00' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '12 Oct 2020 11:59' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 11 Oct 2020 03:53:56 |
| User entered 'Day 27' | System | 11 Oct 2020 03:53:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-12T22:33:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4362ea4b-93d8-43fd-8dfe-4a2468cd5575' | System | 13 Oct 2020 03:33:33 |
| User entered 'None (0)' | System | 13 Oct 2020 03:33:33 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 16:21:09

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-12T22:33:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4362ea4b-93d8-43fd-8dfe-4a2468cd5575' | System | 13 Oct 2020 03:33:33 |
| User entered '12 Oct 2020 22:33' | System | 13 Oct 2020 03:33:33 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '12 Oct 2020 12:00' | System | 11 Oct 2020 03:53:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '13 Oct 2020 11:59' | System | 11 Oct 2020 03:53:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 22 Sep 2020 02:32:30 |
| User entered 'Day 8' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e3b5a14-d04b-416c-b55f-88e0ba60bd11' | System | 24 Sep 2020 03:00:47 |
| User entered 'No interference with activity (1)' | System | 24 Sep 2020 03:00:47 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e3b5a14-d04b-416c-b55f-88e0ba60bd11' | System | 24 Sep 2020 03:00:47 |
| User entered '23 Sep 2020 22:00' | System | 24 Sep 2020 03:00:47 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 02:32:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 23 Sep 2020 04:20:59 |
| User entered 'Day 9' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '95d88cb4-50f8-4fcc-8070-69f6bfe132e8' | System | 25 Sep 2020 03:32:40 |
| User entered 'No interference with activity (1)' | System | 25 Sep 2020 03:32:40 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '95d88cb4-50f8-4fcc-8070-69f6bfe132e8' | System | 25 Sep 2020 03:32:40 |
| User entered '24 Sep 2020 22:32' | System | 25 Sep 2020 03:32:40 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Sep 2020 12:00' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Sep 2020 11:59' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 24 Sep 2020 03:00:47 |
| User entered 'Day 10' | System | 24 Sep 2020 03:00:47 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3e6af303-1f0d-4b99-bffe-2e019e6a1821' | System | 26 Sep 2020 04:21:25 |
| User entered 'No interference with activity (1)' | System | 26 Sep 2020 04:21:25 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3e6af303-1f0d-4b99-bffe-2e019e6a1821' | System | 26 Sep 2020 04:21:25 |
| User entered '25 Sep 2020 23:21' | System | 26 Sep 2020 04:21:25 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 03:00:47 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 03:00:47 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 25 Sep 2020 03:32:40 |
| User entered 'Day 11' | System | 25 Sep 2020 03:32:40 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:32:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f1e2b15d-172b-4483-a1fe-285b73ba9a71' | System | 27 Sep 2020 02:32:12 |
| User entered 'No interference with activity (1)' | System | 27 Sep 2020 02:32:12 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:32:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f1e2b15d-172b-4483-a1fe-285b73ba9a71' | System | 27 Sep 2020 02:32:12 |
| User entered '26 Sep 2020 21:32' | System | 27 Sep 2020 02:32:12 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Sep 2020 12:00' | System | 25 Sep 2020 03:32:40 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Sep 2020 11:59' | System | 25 Sep 2020 03:32:40 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 26 Sep 2020 04:21:25 |
| User entered 'Day 12' | System | 26 Sep 2020 04:21:25 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:53:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '025e5ebe-fa87-422a-864d-06d9c6c918a5' | System | 28 Sep 2020 04:53:07 |
| User entered 'Some interference with activity (2)' | System | 28 Sep 2020 04:53:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:53:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '025e5ebe-fa87-422a-864d-06d9c6c918a5' | System | 28 Sep 2020 04:53:07 |
| User entered '27 Sep 2020 23:53' | System | 28 Sep 2020 04:53:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Sep 2020 12:00' | System | 26 Sep 2020 04:21:25 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Sep 2020 11:59' | System | 26 Sep 2020 04:21:25 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 27 Sep 2020 02:32:12 |
| User entered 'Day 13' | System | 27 Sep 2020 02:32:12 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2955dce2-0581-45a4-b8b7-ab5a3621c203' | System | 29 Sep 2020 02:16:29 |
| User entered 'Some interference with activity (2)' | System | 29 Sep 2020 02:16:29 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2955dce2-0581-45a4-b8b7-ab5a3621c203' | System | 29 Sep 2020 02:16:29 |
| User entered '28 Sep 2020 21:16' | System | 29 Sep 2020 02:16:29 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Sep 2020 12:00' | System | 27 Sep 2020 02:32:12 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Sep 2020 11:59' | System | 27 Sep 2020 02:32:12 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 28 Sep 2020 04:53:07 |
| User entered 'Day 14' | System | 28 Sep 2020 04:53:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:19:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1f50e463-04eb-457f-9804-94c5b9cb8c33' | System | 30 Sep 2020 03:19:15 |
| User entered 'Some interference with activity (2)' | System | 30 Sep 2020 03:19:15 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:19:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1f50e463-04eb-457f-9804-94c5b9cb8c33' | System | 30 Sep 2020 03:19:15 |
| User entered '29 Sep 2020 22:19' | System | 30 Sep 2020 03:19:15 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 04:53:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 04:53:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 29 Sep 2020 02:16:29 |
| User entered 'Day 15' | System | 29 Sep 2020 02:16:29 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:04:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b409b7d8-3e6f-4ea6-8676-6bf0e6dd0b8c' | System | 01 Oct 2020 01:04:11 |
| User entered 'Some interference with activity (2)' | System | 01 Oct 2020 01:04:11 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:04:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b409b7d8-3e6f-4ea6-8676-6bf0e6dd0b8c' | System | 01 Oct 2020 01:04:11 |
| User entered '30 Sep 2020 20:04' | System | 01 Oct 2020 01:04:11 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Sep 2020 12:00' | System | 29 Sep 2020 02:16:29 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '01 Oct 2020 11:59' | System | 29 Sep 2020 02:16:29 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 30 Sep 2020 03:19:15 |
| User entered 'Day 16' | System | 30 Sep 2020 03:19:15 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e8827a7d-2009-46e7-bb0d-5f1f38df87a4' | System | 02 Oct 2020 03:27:56 |
| User entered 'No interference with activity (1)' | System | 02 Oct 2020 03:27:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e8827a7d-2009-46e7-bb0d-5f1f38df87a4' | System | 02 Oct 2020 03:27:56 |
| User entered '01 Oct 2020 22:27' | System | 02 Oct 2020 03:27:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '01 Oct 2020 12:00' | System | 30 Sep 2020 03:19:15 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '02 Oct 2020 11:59' | System | 30 Sep 2020 03:19:15 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 01 Oct 2020 01:04:11 |
| User entered 'Day 17' | System | 01 Oct 2020 01:04:11 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '02 Oct 2020 12:00' | System | 01 Oct 2020 01:04:11 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '03 Oct 2020 11:59' | System | 01 Oct 2020 01:04:11 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 02 Oct 2020 03:27:56 |
| User entered 'Day 18' | System | 02 Oct 2020 03:27:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:23:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd4dd70cf-05e6-4713-8ad8-2e5fdf232eda' | System | 04 Oct 2020 03:23:07 |
| User entered 'No interference with activity (1)' | System | 04 Oct 2020 03:23:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:23:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd4dd70cf-05e6-4713-8ad8-2e5fdf232eda' | System | 04 Oct 2020 03:23:07 |
| User entered '03 Oct 2020 22:23' | System | 04 Oct 2020 03:23:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '03 Oct 2020 12:00' | System | 02 Oct 2020 03:27:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '04 Oct 2020 11:59' | System | 02 Oct 2020 03:27:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 04 Oct 2020 03:23:07 |
| User entered 'Day 19' | System | 04 Oct 2020 03:23:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:46:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '561b9f0a-c8c3-4028-a5c4-d3062ee6b262' | System | 05 Oct 2020 04:46:59 |
| User entered 'No interference with activity (1)' | System | 05 Oct 2020 04:46:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:46:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '561b9f0a-c8c3-4028-a5c4-d3062ee6b262' | System | 05 Oct 2020 04:46:59 |
| User entered '04 Oct 2020 23:46' | System | 05 Oct 2020 04:46:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '04 Oct 2020 12:00' | System | 04 Oct 2020 03:23:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '05 Oct 2020 11:59' | System | 04 Oct 2020 03:23:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 04 Oct 2020 03:23:07 |
| User entered 'Day 20' | System | 04 Oct 2020 03:23:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '05 Oct 2020 12:00' | System | 04 Oct 2020 03:23:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '06 Oct 2020 11:59' | System | 04 Oct 2020 03:23:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 05 Oct 2020 04:46:59 |
| User entered 'Day 21' | System | 05 Oct 2020 04:46:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5e24ebfd-c6af-4d62-8b15-85bf647026a9' User entered 'None (0)' | System | 07 Oct 2020 05:07:22 |
| | System | 07 Oct 2020 05:07:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5e24ebfd-c6af-4d62-8b15-85bf647026a9' User entered '07 Oct 2020 00:07' | System | 07 Oct 2020 05:07:22 |
| | System | 07 Oct 2020 05:07:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '06 Oct 2020 12:00' | System | 05 Oct 2020 04:46:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '07 Oct 2020 11:59' | System | 05 Oct 2020 04:46:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 23 Sep 2020 04:20:59 |
| User entered 'Day 8' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8de993af-4cc6-4ff1-82a4-41188e31dc95' | System | 24 Sep 2020 03:00:57 |
| User entered 'Some interference with activity (2)' | System | 24 Sep 2020 03:00:57 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8de993af-4cc6-4ff1-82a4-41188e31dc95' | System | 24 Sep 2020 03:00:57 |
| User entered '23 Sep 2020 22:00' | System | 24 Sep 2020 03:00:57 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Sep 2020 12:00' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Sep 2020 11:59' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 23 Sep 2020 04:20:59 |
| User entered 'Day 9' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c0c6d1f7-6141-4c37-bf9e-5d7a569e1f7f' | System | 25 Sep 2020 03:32:46 |
| User entered 'Some interference with activity (2)' | System | 25 Sep 2020 03:32:46 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c0c6d1f7-6141-4c37-bf9e-5d7a569e1f7f' User entered '24 Sep 2020 22:32' | System | 25 Sep 2020 03:32:46 |
| | System | 25 Sep 2020 03:32:46 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Sep 2020 12:00' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Sep 2020 11:59' | System | 23 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 24 Sep 2020 03:00:57 |
| User entered 'Day 10' | System | 24 Sep 2020 03:00:57 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b110ef58-88f9-4610-82d1-9b260ed63e39' | System | 26 Sep 2020 04:21:31 |
| User entered 'Some interference with activity (2)' | System | 26 Sep 2020 04:21:31 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:27', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b110ef58-88f9-4610-82d1-9b260ed63e39' | System | 26 Sep 2020 04:21:31 |
| User entered '25 Sep 2020 23:21' | System | 26 Sep 2020 04:21:31 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 03:00:57 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 03:00:57 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 25 Sep 2020 03:32:46 |
| User entered 'Day 11' | System | 25 Sep 2020 03:32:46 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:32:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '434b03b3-71de-4bc3-87f1-c9dfa0507e81' | System | 27 Sep 2020 02:32:36 |
| User entered 'No interference with activity (1)' | System | 27 Sep 2020 02:32:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:32:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '434b03b3-71de-4bc3-87f1-c9dfa0507e81' | System | 27 Sep 2020 02:32:36 |
| User entered '26 Sep 2020 21:32' | System | 27 Sep 2020 02:32:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Sep 2020 12:00' | System | 25 Sep 2020 03:32:46 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Sep 2020 11:59' | System | 25 Sep 2020 03:32:46 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 26 Sep 2020 04:21:31 |
| User entered 'Day 12' | System | 26 Sep 2020 04:21:31 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:53:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f71ba276-06aa-48f9-ac77-667ab2150a8d' | System | 28 Sep 2020 04:53:14 |
| User entered 'No interference with activity (1)' | System | 28 Sep 2020 04:53:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:53:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f71ba276-06aa-48f9-ac77-667ab2150a8d' | System | 28 Sep 2020 04:53:14 |
| User entered '27 Sep 2020 23:53' | System | 28 Sep 2020 04:53:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Sep 2020 12:00' | System | 26 Sep 2020 04:21:31 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Sep 2020 11:59' | System | 26 Sep 2020 04:21:31 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 27 Sep 2020 02:32:36 |
| User entered 'Day 13' | System | 27 Sep 2020 02:32:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9c3ad15b-4656-40e8-9de8-9557d6fded45' | System | 29 Sep 2020 02:16:36 |
| User entered 'Some interference with activity (2)' | System | 29 Sep 2020 02:16:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9c3ad15b-4656-40e8-9de8-9557d6fded45' | System | 29 Sep 2020 02:16:36 |
| User entered '28 Sep 2020 21:16' | System | 29 Sep 2020 02:16:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Sep 2020 12:00' | System | 27 Sep 2020 02:32:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Sep 2020 11:59' | System | 27 Sep 2020 02:32:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 28 Sep 2020 04:53:14 |
| User entered 'Day 14' | System | 28 Sep 2020 04:53:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:19:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6da67b42-4dfc-408e-8326-1ad938c59056' | System | 30 Sep 2020 03:19:19 |
| User entered 'Some interference with activity (2)' | System | 30 Sep 2020 03:19:19 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:19:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6da67b42-4dfc-408e-8326-1ad938c59056' | System | 30 Sep 2020 03:19:19 |
| User entered '29 Sep 2020 22:19' | System | 30 Sep 2020 03:19:19 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 04:53:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 04:53:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 29 Sep 2020 02:16:36 |
| User entered 'Day 15' | System | 29 Sep 2020 02:16:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:04:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '59e80a18-c02d-4071-98f8-0d9c2ecb9081' | System | 01 Oct 2020 01:04:18 |
| User entered 'Some interference with activity (2)' | System | 01 Oct 2020 01:04:18 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:04:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '59e80a18-c02d-4071-98f8-0d9c2ecb9081' | System | 01 Oct 2020 01:04:18 |
| User entered '30 Sep 2020 20:04' | System | 01 Oct 2020 01:04:18 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Sep 2020 12:00' | System | 29 Sep 2020 02:16:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '01 Oct 2020 11:59' | System | 29 Sep 2020 02:16:36 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 30 Sep 2020 03:19:19 |
| User entered 'Day 16' | System | 30 Sep 2020 03:19:19 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1afb0ab-d4df-4ccc-8f6a-5544d9e11f14' | System | 02 Oct 2020 03:28:05 |
| User entered 'No interference with activity (1)' | System | 02 Oct 2020 03:28:05 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1afb0ab-d4df-4ccc-8f6a-5544d9e11f14' | System | 02 Oct 2020 03:28:05 |
| User entered '01 Oct 2020 22:27' | System | 02 Oct 2020 03:28:05 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '01 Oct 2020 12:00' | System | 30 Sep 2020 03:19:19 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '02 Oct 2020 11:59' | System | 30 Sep 2020 03:19:19 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 01 Oct 2020 01:04:18 |
| User entered 'Day 17' | System | 01 Oct 2020 01:04:18 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '02 Oct 2020 12:00' | System | 01 Oct 2020 01:04:18 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '03 Oct 2020 11:59' | System | 01 Oct 2020 01:04:18 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 02 Oct 2020 03:28:05 |
| User entered 'Day 18' | System | 02 Oct 2020 03:28:05 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:23:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c62a3c8-5ae8-4f8a-831d-71275dec0918' | System | 04 Oct 2020 03:23:13 |
| User entered 'Some interference with activity (2)' | System | 04 Oct 2020 03:23:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:23:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c62a3c8-5ae8-4f8a-831d-71275dec0918' | System | 04 Oct 2020 03:23:13 |
| User entered '03 Oct 2020 22:23' | System | 04 Oct 2020 03:23:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '03 Oct 2020 12:00' | System | 02 Oct 2020 03:28:05 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '04 Oct 2020 11:59' | System | 02 Oct 2020 03:28:05 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 04 Oct 2020 03:23:13 |
| User entered 'Day 19' | System | 04 Oct 2020 03:23:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:47:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1d964f56-ea06-40be-b8bd-76cce72609b1' | System | 05 Oct 2020 04:47:07 |
| User entered 'No interference with activity (1)' | System | 05 Oct 2020 04:47:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:47:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1d964f56-ea06-40be-b8bd-76cce72609b1' | System | 05 Oct 2020 04:47:07 |
| User entered '04 Oct 2020 23:47' | System | 05 Oct 2020 04:47:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '04 Oct 2020 12:00' | System | 04 Oct 2020 03:23:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '05 Oct 2020 11:59' | System | 04 Oct 2020 03:23:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 04 Oct 2020 03:23:13 |
| User entered 'Day 20' | System | 04 Oct 2020 03:23:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '05 Oct 2020 12:00' | System | 04 Oct 2020 03:23:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '06 Oct 2020 11:59' | System | 04 Oct 2020 03:23:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 05 Oct 2020 04:47:07 |
| User entered 'Day 21' | System | 05 Oct 2020 04:47:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 16:21:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a62d7486-236b-4cae-b72d-4ef21db5a430' | System | 07 Oct 2020 05:07:33 |
| User entered 'None (0)' | System | 07 Oct 2020 05:07:33 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a62d7486-236b-4cae-b72d-4ef21db5a430' | System | 07 Oct 2020 05:07:33 |
| User entered '07 Oct 2020 00:07' | System | 07 Oct 2020 05:07:33 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '06 Oct 2020 12:00' | System | 05 Oct 2020 04:47:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '07 Oct 2020 11:59' | System | 05 Oct 2020 04:47:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 22 Sep 2020 02:31:45 |
| User entered 'Day 8' | System | 22 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25d1fb09-5152-48ba-a192-ae35e2e15b4f' | System | 24 Sep 2020 03:01:08 |
| User entered 'No (N)' | System | 24 Sep 2020 03:01:08 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:01:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25d1fb09-5152-48ba-a192-ae35e2e15b4f' | System | 24 Sep 2020 03:01:08 |
| User entered '23 Sep 2020 22:01' | System | 24 Sep 2020 03:01:08 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 23 Sep 2020 04:20:03 |
| User entered 'Day 9' | System | 23 Sep 2020 04:20:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9793de78-67a3-4e1d-9450-3246b5b49f90' | System | 25 Sep 2020 03:33:00 |
| User entered 'No (N)' | System | 25 Sep 2020 03:33:00 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9793de78-67a3-4e1d-9450-3246b5b49f90' | System | 25 Sep 2020 03:33:00 |
| User entered '24 Sep 2020 22:32' | System | 25 Sep 2020 03:33:00 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '24 Sep 2020 12:00' | System | 23 Sep 2020 04:20:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Sep 2020 11:59' | System | 23 Sep 2020 04:20:03 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 24 Sep 2020 03:00:24 |
| User entered 'Day 10' | System | 24 Sep 2020 03:00:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:35', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9e423f0-ff6b-491a-abc6-00a21a5b6c73' | System | 26 Sep 2020 04:21:40 |
| User entered 'No (N)' | System | 26 Sep 2020 04:21:40 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9e423f0-ff6b-491a-abc6-00a21a5b6c73' | System | 26 Sep 2020 04:21:40 |
| User entered '25 Sep 2020 23:21' | System | 26 Sep 2020 04:21:40 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 03:00:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 03:00:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 25 Sep 2020 03:32:16 |
| User entered 'Day 11' | System | 25 Sep 2020 03:32:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:32:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2508a219-44a1-4fea-bcb9-06a97436275a' | System | 27 Sep 2020 02:32:43 |
| User entered 'No (N)' | System | 27 Sep 2020 02:32:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:32:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2508a219-44a1-4fea-bcb9-06a97436275a' | System | 27 Sep 2020 02:32:43 |
| User entered '26 Sep 2020 21:32' | System | 27 Sep 2020 02:32:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '26 Sep 2020 12:00' | System | 25 Sep 2020 03:32:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Sep 2020 11:59' | System | 25 Sep 2020 03:32:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 26 Sep 2020 04:20:59 |
| User entered 'Day 12' | System | 26 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:53:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a0460a82-d959-4045-b45a-01320d685485' | System | 28 Sep 2020 04:53:24 |
| User entered 'No (N)' | System | 28 Sep 2020 04:53:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:53:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a0460a82-d959-4045-b45a-01320d685485' | System | 28 Sep 2020 04:53:24 |
| User entered '27 Sep 2020 23:53' | System | 28 Sep 2020 04:53:24 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '27 Sep 2020 12:00' | System | 26 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Sep 2020 11:59' | System | 26 Sep 2020 04:20:59 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 27 Sep 2020 02:31:45 |
| User entered 'Day 13' | System | 27 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a94c3640-7ac9-4d8c-8f1a-ba78311cfbc6' | System | 29 Sep 2020 02:16:49 |
| User entered 'Yes (Y)' | System | 29 Sep 2020 02:16:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a94c3640-7ac9-4d8c-8f1a-ba78311cfbc6' | System | 29 Sep 2020 02:16:49 |
| User entered '28 Sep 2020 21:16' | System | 29 Sep 2020 02:16:49 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '28 Sep 2020 12:00' | System | 27 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Sep 2020 11:59' | System | 27 Sep 2020 02:31:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 28 Sep 2020 04:52:43 |
| User entered 'Day 14' | System | 28 Sep 2020 04:52:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:19:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '94437ca2-55d3-486c-82d3-30d018c929dc' | System | 30 Sep 2020 03:19:25 |
| User entered 'No (N)' | System | 30 Sep 2020 03:19:25 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:19:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '94437ca2-55d3-486c-82d3-30d018c929dc' | System | 30 Sep 2020 03:19:25 |
| User entered '29 Sep 2020 22:19' | System | 30 Sep 2020 03:19:25 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 04:52:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 04:52:43 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 29 Sep 2020 02:15:54 |
| User entered 'Day 15' | System | 29 Sep 2020 02:15:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:04:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3dbe58e1-10b1-45c8-b93c-378cefbdc508' | System | 01 Oct 2020 01:04:22 |
| User entered 'No (N)' | System | 01 Oct 2020 01:04:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:04:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3dbe58e1-10b1-45c8-b93c-378cefbdc508' | System | 01 Oct 2020 01:04:22 |
| User entered '30 Sep 2020 20:04' | System | 01 Oct 2020 01:04:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '30 Sep 2020 12:00' | System | 29 Sep 2020 02:15:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '01 Oct 2020 11:59' | System | 29 Sep 2020 02:15:54 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 30 Sep 2020 03:18:52 |
| User entered 'Day 16' | System | 30 Sep 2020 03:18:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:28:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c3646ec9-e86d-448c-977f-7f8c3aa26e5c' | System | 02 Oct 2020 03:28:07 |
| User entered 'No (N)' | System | 02 Oct 2020 03:28:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:28:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c3646ec9-e86d-448c-977f-7f8c3aa26e5c' | System | 02 Oct 2020 03:28:07 |
| User entered '01 Oct 2020 22:28' | System | 02 Oct 2020 03:28:07 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '01 Oct 2020 12:00' | System | 30 Sep 2020 03:18:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '02 Oct 2020 11:59' | System | 30 Sep 2020 03:18:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 01 Oct 2020 01:03:52 |
| User entered 'Day 17' | System | 01 Oct 2020 01:03:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '02 Oct 2020 12:00' | System | 01 Oct 2020 01:03:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '03 Oct 2020 11:59' | System | 01 Oct 2020 01:03:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 02 Oct 2020 03:27:45 |
| User entered 'Day 18' | System | 02 Oct 2020 03:27:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:23:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f84f0687-a171-4e7d-9c58-fb140a3fa796' | System | 04 Oct 2020 03:23:19 |
| User entered 'No (N)' | System | 04 Oct 2020 03:23:19 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:23:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f84f0687-a171-4e7d-9c58-fb140a3fa796' | System | 04 Oct 2020 03:23:19 |
| User entered '03 Oct 2020 22:23' | System | 04 Oct 2020 03:23:19 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '03 Oct 2020 12:00' | System | 02 Oct 2020 03:27:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '04 Oct 2020 11:59' | System | 02 Oct 2020 03:27:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 04 Oct 2020 03:22:52 |
| User entered 'Day 19' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:47:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '76fb7aed-4c9b-4da8-93c2-b5ff0e646128' | System | 05 Oct 2020 04:47:14 |
| User entered 'No (N)' | System | 05 Oct 2020 04:47:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:47:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '76fb7aed-4c9b-4da8-93c2-b5ff0e646128' | System | 05 Oct 2020 04:47:14 |
| User entered '04 Oct 2020 23:47' | System | 05 Oct 2020 04:47:14 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '04 Oct 2020 12:00' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '05 Oct 2020 11:59' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 04 Oct 2020 03:22:52 |
| User entered 'Day 20' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '05 Oct 2020 12:00' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '06 Oct 2020 11:59' | System | 04 Oct 2020 03:22:52 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 05 Oct 2020 04:46:45 |
| User entered 'Day 21' | System | 05 Oct 2020 04:46:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'faaad91e-850f-439d-8d09-f2a3a36419e9' | System | 07 Oct 2020 05:07:38 |
| User entered 'No (N)' | System | 07 Oct 2020 05:07:38 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:35', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'faaad91e-850f-439d-8d09-f2a3a36419e9' User entered '07 Oct 2020 00:07' | System | 07 Oct 2020 05:07:38 |
| | System | 07 Oct 2020 05:07:38 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '06 Oct 2020 12:00' | System | 05 Oct 2020 04:46:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '07 Oct 2020 11:59' | System | 05 Oct 2020 04:46:45 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 07 Oct 2020 05:07:16 |
| User entered 'Day 23' | System | 07 Oct 2020 05:07:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| | | |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '08 Oct 2020 12:00' | System | 07 Oct 2020 05:07:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '09 Oct 2020 11:59' | System | 07 Oct 2020 05:07:16 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 08 Oct 2020 02:04:13 |
| User entered 'Day 24' | System | 08 Oct 2020 02:04:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-09T22:02:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7897f052-359b-4cca-a879-a9b2dadf20b1' | System | 10 Oct 2020 03:02:30 |
| User entered 'No (N)' | System | 10 Oct 2020 03:02:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-09T22:02:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7897f052-359b-4cca-a879-a9b2dadf20b1' | System | 10 Oct 2020 03:02:30 |
| User entered '09 Oct 2020 22:02' | System | 10 Oct 2020 03:02:30 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '09 Oct 2020 12:00' | System | 08 Oct 2020 02:04:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '10 Oct 2020 11:59' | System | 08 Oct 2020 02:04:13 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 10 Oct 2020 03:02:22 |
| User entered 'Day 25' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-10T22:53:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c5eeb3bd-4fd5-4ec9-9aac-c1ab15f63f8c' | System | 11 Oct 2020 03:54:00 |
| User entered 'No (N)' | System | 11 Oct 2020 03:54:00 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-10T22:53:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c5eeb3bd-4fd5-4ec9-9aac-c1ab15f63f8c' | System | 11 Oct 2020 03:54:00 |
| User entered '10 Oct 2020 22:53' | System | 11 Oct 2020 03:54:00 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '10 Oct 2020 12:00' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '11 Oct 2020 11:59' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 10 Oct 2020 03:02:22 |
| User entered 'Day 26' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-12T00:04:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'cf0b4f78-2695-446f-8b15-64aacbd6f4b9' | System | 12 Oct 2020 05:04:12 |
| User entered 'No (N)' | System | 12 Oct 2020 05:04:12 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-12T00:04:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'cf0b4f78-2695-446f-8b15-64aacbd6f4b9' | System | 12 Oct 2020 05:04:12 |
| User entered '12 Oct 2020 00:04' | System | 12 Oct 2020 05:04:12 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '11 Oct 2020 12:00' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '12 Oct 2020 11:59' | System | 10 Oct 2020 03:02:22 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 11 Oct 2020 03:53:56 |
| User entered 'Day 27' | System | 11 Oct 2020 03:53:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:21:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-12T22:33:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c28ef9b7-3357-40a2-a240-908ee319f2c4' | System | 13 Oct 2020 03:33:39 |
| User entered 'No (N)' | System | 13 Oct 2020 03:33:39 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:21:09

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-12T22:33:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c28ef9b7-3357-40a2-a240-908ee319f2c4' | System | 13 Oct 2020 03:33:39 |
| User entered '12 Oct 2020 22:33' | System | 13 Oct 2020 03:33:39 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:21:09

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '12 Oct 2020 12:00' | System | 11 Oct 2020 03:53:56 |

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:21:09

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| User entered '13 Oct 2020 11:59' | System | 11 Oct 2020 03:53:56 |

US3272169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:50:38 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Sep 2020 19:47:51 |

US3272169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:50:38 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '23 Sep 2020' | (b) (4), (b) (6) | 23 Sep 2020 19:47:51 |

US3272169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:50:38 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 23 Sep 2020 19:47:51 |

US3272169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:50:38 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 23 Sep 2020 19:47:51 |

US3272169

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:50:38 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Sep 2020 19:47:53 |

US3272169

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:50:38 |
| User entered 'I' | System | 23 Sep 2020 19:47:53 |

US3272169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:44:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:26:01 |

US3272169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:44:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '30 Sep 2020' | (b) (4), (b) (6) | 30 Sep 2020 15:26:01 |

US3272169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:44:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 30 Sep 2020 15:26:01 |

US3272169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:44:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:26:01 |

US3272169

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:44:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:26:09 |

US3272169

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:44:11 |
| User entered 'I' | System | 30 Sep 2020 15:26:09 |

US3272169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 05:20:49 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Oct 2020 18:34:44 |

US3272169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 05:20:49 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '08 Oct 2020' | (b) (4), (b) (6) | 08 Oct 2020 18:34:44 |

US3272169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 05:20:49 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 08 Oct 2020 18:34:44 |

US3272169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 05:20:49 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 08 Oct 2020 18:34:44 |

US3272169

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 05:20:49 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Oct 2020 18:34:55 |

US3272169

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 05:20:49 |
| User entered 'I' | System | 08 Oct 2020 18:34:55 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 17:40:48 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '14 Oct 2020' | (b) (4), (b) (6) | 14 Oct 2020 17:40:48 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 14 Oct 2020 17:40:48 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User entered 'VISIT3' | System | 14 Oct 2020 17:40:48 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '14 Oct 2020' | (b) (4), (b) (6) | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '10:45' | (b) (4), (b) (6) | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User entered '14 Oct 2020 10:45' | System | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '36.7' C | (b) (4), (b) (6) | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '82' | (b) (4), (b) (6) | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User entered 'bpm' | System | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '12' | (b) (4), (b) (6) | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User entered 'breaths/min' | System | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '88' | (b) (4), (b) (6) | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User entered 'mmHg' | System | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '62' | (b) (4), (b) (6) | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User entered 'mmHg' | System | 14 Oct 2020 17:13:23 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| | | |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| | | |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:09

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 17:13:32 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:09

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '14 Oct 2020' | (b) (4), (b) (6) | 14 Oct 2020 17:13:32 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 17:14:11 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '14 Oct 2020' | (b) (4), (b) (6) | 14 Oct 2020 17:14:11 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '11:10' | (b) (4), (b) (6) | 14 Oct 2020 17:14:11 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User entered '14 Oct 2020 11:10' | System | 14 Oct 2020 17:14:11 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 17:14:27 |

US3272169

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:17:23 |
| User entered 'I' | System | 14 Oct 2020 17:14:27 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 64' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-15T21:35:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '715a9e23-feb4-49b5-9344-ca7a5c026a61' | System | 16 Oct 2020 02:35:17 |
| User entered 'No (N)' | System | 16 Oct 2020 02:35:17 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you been exposed to someone with 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) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-15T21:35:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '715a9e23-feb4-49b5-9344-ca7a5c026a61' | System | 16 Oct 2020 02:35:17 |
| User entered 'No (N)' | System | 16 Oct 2020 02:35:17 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-15T21:35:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '715a9e23-feb4-49b5-9344-ca7a5c026a61' | System | 16 Oct 2020 02:35:17 |
| User entered '15 Oct 2020 21:35:16' | System | 16 Oct 2020 02:35:17 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered '15 Oct 2020 00:01' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered '19 Oct 2020 23:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 71' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-22T00:59:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd2fee350-19b7-49d1-8518-89fe8ea4798f' | System | 22 Oct 2020 05:59:43 |
| User entered 'No (N)' | System | 22 Oct 2020 05:59:43 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you been exposed to someone with 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) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-22T00:59:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd2fee350-19b7-49d1-8518-89fe8ea4798f' | System | 22 Oct 2020 05:59:43 |
| User entered 'No (N)' | System | 22 Oct 2020 05:59:43 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-22T00:59:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd2fee350-19b7-49d1-8518-89fe8ea4798f' User entered '22 Oct 2020 00:59:38' | System | 22 Oct 2020 05:59:43 |
| | System | 22 Oct 2020 05:59:43 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered '22 Oct 2020 00:01' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered '26 Oct 2020 23:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 78' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-29T22:26:58', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '99d7c90d-6422-40fd-8b4c-6c335a311e35' | System | 30 Oct 2020 03:27:14 |
| User entered 'No (N)' | System | 30 Oct 2020 03:27:14 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you been exposed to someone with 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) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-29T22:26:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '99d7c90d-6422-40fd-8b4c-6c335a311e35' | System | 30 Oct 2020 03:27:14 |
| User entered 'No (N)' | System | 30 Oct 2020 03:27:14 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-29T22:27:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '99d7c90d-6422-40fd-8b4c-6c335a311e35' | System | 30 Oct 2020 03:27:14 |
| User entered '29 Oct 2020 22:27:09' | System | 30 Oct 2020 03:27:14 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered '29 Oct 2020 00:01' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered '02 Nov 2020 23:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 92' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-12T21:09:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94' | System | 13 Nov 2020 03:10:23 |
| User entered 'Yes (Y)' | System | 13 Nov 2020 03:10:23 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you been exposed to someone with 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) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-12T21:09:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94' | System | 13 Nov 2020 03:10:23 |
| User entered 'Yes (Y)' | System | 13 Nov 2020 03:10:23 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-12T21:09:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94' | System | 13 Nov 2020 03:10:23 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 13 Nov 2020 03:10:23 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-12T21:09:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94' | System | 13 Nov 2020 03:10:23 |
| User entered 'No (N)' | System | 13 Nov 2020 03:10:23 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-12T21:10:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94' | System | 13 Nov 2020 03:10:23 |
| User entered 'Yes (Y)' | System | 13 Nov 2020 03:10:23 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-12T21:10:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94' | System | 13 Nov 2020 03:10:23 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 13 Nov 2020 03:10:23 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-12T21:10:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94' | System | 13 Nov 2020 03:10:23 |
| User entered '12 Nov 2020 21:10:14' | System | 13 Nov 2020 03:10:23 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered '12 Nov 2020 00:01' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:21:50 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered '16 Nov 2020 23:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered 'Day 99' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you been exposed to someone with 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) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered '19 Nov 2020 00:01' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 08:38:42 |
| Data entry locked. | System | 15 Aug 2020 20:07:42 |
| User entered '23 Nov 2020 23:59' | System | 15 Aug 2020 20:07:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2020-11-19T21:13:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9eef5d2b-8d44-4dbb-aa8a-d09ac5ee1c2d' | System | 20 Nov 2020 03:13:20 |
| User entered 'No (N)' | System | 20 Nov 2020 03:13:20 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-11-19T21:13:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9eef5d2b-8d44-4dbb-aa8a-d09ac5ee1c2d' | System | 20 Nov 2020 03:13:20 |
| User entered 'No (N)' | System | 20 Nov 2020 03:13:20 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-19T21:13:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9eef5d2b-8d44-4dbb-aa8a-d09ac5ee1c2d' | System | 20 Nov 2020 03:13:20 |
| User entered '19 Nov 2020 21:13:17' | System | 20 Nov 2020 03:13:20 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '16 Nov 2020 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '20 Nov 2020 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2020-11-23T22:17:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8da812ce-dd0f-4a64-af6b-aaa3a03a5d8f' | System | 24 Nov 2020 04:17:30 |
| User entered 'No (N)' | System | 24 Nov 2020 04:17:30 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-11-23T22:17:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8da812ce-dd0f-4a64-af6b-aaa3a03a5d8f' | System | 24 Nov 2020 04:17:30 |
| User entered 'No (N)' | System | 24 Nov 2020 04:17:30 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-23T22:17:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8da812ce-dd0f-4a64-af6b-aaa3a03a5d8f' | System | 24 Nov 2020 04:17:30 |
| User entered '23 Nov 2020 22:17:26' | System | 24 Nov 2020 04:17:30 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '23 Nov 2020 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '27 Nov 2020 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2020-11-30T10:29:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ea08f8f2-763e-4e34-bcb7-2d30fcb7d731' | System | 30 Nov 2020 16:29:27 |
| User entered 'No (N)' | System | 30 Nov 2020 16:29:27 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-11-30T10:29:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ea08f8f2-763e-4e34-bcb7-2d30fcb7d731' | System | 30 Nov 2020 16:29:27 |
| User entered 'No (N)' | System | 30 Nov 2020 16:29:27 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-30T10:29:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ea08f8f2-763e-4e34-bcb7-2d30fcb7d731' | System | 30 Nov 2020 16:29:27 |
| User entered '30 Nov 2020 10:29:20' | System | 30 Nov 2020 16:29:27 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '30 Nov 2020 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '04 Dec 2020 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2020-12-07T19:19:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '50b5fa74-f0e9-450d-a12a-964eefc1e5c3' | System | 08 Dec 2020 01:19:46 |
| User entered 'No (N)' | System | 08 Dec 2020 01:19:46 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-12-07T19:19:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '50b5fa74-f0e9-450d-a12a-964eefc1e5c3' | System | 08 Dec 2020 01:19:46 |
| User entered 'No (N)' | System | 08 Dec 2020 01:19:46 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-12-07T19:19:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '50b5fa74-f0e9-450d-a12a-964eefc1e5c3' | System | 08 Dec 2020 01:19:46 |
| User entered '07 Dec 2020 19:19:44' | System | 08 Dec 2020 01:19:46 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '07 Dec 2020 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '11 Dec 2020 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2020-12-14T07:54:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6743faa6-acd2-400a-a974-f0c53f74c3da' | System | 14 Dec 2020 13:54:40 |
| User entered 'No (N)' | System | 14 Dec 2020 13:54:40 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-12-14T07:54:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6743faa6-acd2-400a-a974-f0c53f74c3da' | System | 14 Dec 2020 13:54:40 |
| User entered 'No (N)' | System | 14 Dec 2020 13:54:40 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-12-14T07:54:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6743faa6-acd2-400a-a974-f0c53f74c3da' User entered '14 Dec 2020 07:54:39' | System | 14 Dec 2020 13:54:40 |
| | System | 14 Dec 2020 13:54:40 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '14 Dec 2020 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '18 Dec 2020 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2020-12-21T00:01:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '362c2102-a72e-4c05-8a60-10181ee0fc1f' | System | 21 Dec 2020 06:01:58 |
| User entered 'No (N)' | System | 21 Dec 2020 06:01:58 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-12-21T00:01:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '362c2102-a72e-4c05-8a60-10181ee0fc1f' | System | 21 Dec 2020 06:01:58 |
| User entered 'No (N)' | System | 21 Dec 2020 06:01:58 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-12-21T00:01:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '362c2102-a72e-4c05-8a60-10181ee0fc1f' User entered '21 Dec 2020 00:01:57' | System | 21 Dec 2020 06:01:58 |
| | System | 21 Dec 2020 06:01:58 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '21 Dec 2020 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '25 Dec 2020 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2020-12-28T23:38:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4bab56f6-d079-481a-8b93-e145808c0dcb' | System | 29 Dec 2020 05:38:05 |
| User entered 'No (N)' | System | 29 Dec 2020 05:38:05 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-12-28T23:38:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4bab56f6-d079-481a-8b93-e145808c0dcb' | System | 29 Dec 2020 05:38:05 |
| User entered 'No (N)' | System | 29 Dec 2020 05:38:05 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-12-28T23:38:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4bab56f6-d079-481a-8b93-e145808c0dcb' User entered '28 Dec 2020 23:38:06' | System | 29 Dec 2020 05:38:05 |
| | System | 29 Dec 2020 05:38:05 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '28 Dec 2020 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '01 Jan 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-01-04T06:58:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0f7a2a02-02b7-4c87-9b6e-4ec77149fa3a' | System | 04 Jan 2021 12:58:47 |
| User entered 'No (N)' | System | 04 Jan 2021 12:58:47 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-01-04T06:58:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0f7a2a02-02b7-4c87-9b6e-4ec77149fa3a' | System | 04 Jan 2021 12:58:47 |
| User entered 'No (N)' | System | 04 Jan 2021 12:58:47 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-01-04T06:58:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0f7a2a02-02b7-4c87-9b6e-4ec77149fa3a' | System | 04 Jan 2021 12:58:47 |
| User entered '04 Jan 2021 06:58:48' | System | 04 Jan 2021 12:58:47 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '04 Jan 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '08 Jan 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-01-11T06:47:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'aeaec310-ed2-467e-a134-452f9b0ef19f' | System | 11 Jan 2021 12:47:12 |
| User entered 'No (N)' | System | 11 Jan 2021 12:47:12 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-01-11T06:47:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'aeaec310-ed2-467e-a134-452f9b0ef19f' | System | 11 Jan 2021 12:47:12 |
| User entered 'No (N)' | System | 11 Jan 2021 12:47:12 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-01-11T06:47:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'aeaec310-ed2-467e-a134-452f9b0ef19f' | System | 11 Jan 2021 12:47:12 |
| User entered '11 Jan 2021 06:47:09' | System | 11 Jan 2021 12:47:12 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '11 Jan 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '15 Jan 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-01-18T07:00:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e62e816b-4119-4bcd-88c3-eb4803f97c88' | System | 18 Jan 2021 13:01:09 |
| User entered 'No (N)' | System | 18 Jan 2021 13:01:09 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-01-18T07:01:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e62e816b-4119-4bcd-88c3-eb4803f97c88' | System | 18 Jan 2021 13:01:09 |
| User entered 'No (N)' | System | 18 Jan 2021 13:01:09 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-01-18T07:01:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e62e816b-4119-4bcd-88c3-eb4803f97c88' User entered '18 Jan 2021 07:01:06' | System | 18 Jan 2021 13:01:09 |
| | System | 18 Jan 2021 13:01:09 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '18 Jan 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '22 Jan 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-01-25T06:59:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4b07dfc2-1c1a-4215-817b-1892a1fbcf95' | System | 25 Jan 2021 12:59:40 |
| User entered 'No (N)' | System | 25 Jan 2021 12:59:40 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-01-25T06:59:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4b07dfc2-1c1a-4215-817b-1892a1fbcf95' | System | 25 Jan 2021 12:59:40 |
| User entered 'No (N)' | System | 25 Jan 2021 12:59:40 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-01-25T06:59:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4b07dfc2-1c1a-4215-817b-1892a1fbcf95' | System | 25 Jan 2021 12:59:40 |
| User entered '25 Jan 2021 06:59:37' | System | 25 Jan 2021 12:59:40 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '25 Jan 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '29 Jan 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-02-01T07:02:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0e396b39-b516-4df3-8ba0-ce018c0c34c0' | System | 01 Feb 2021 13:02:23 |
| User entered 'No (N)' | System | 01 Feb 2021 13:02:23 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-02-01T07:02:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0e396b39-b516-4df3-8ba0-ce018c0c34c0' | System | 01 Feb 2021 13:02:23 |
| User entered 'No (N)' | System | 01 Feb 2021 13:02:23 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-02-01T07:02:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0e396b39-b516-4df3-8ba0-ce018c0c34c0' | System | 01 Feb 2021 13:02:23 |
| User entered '01 Feb 2021 07:02:23' | System | 01 Feb 2021 13:02:23 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '01 Feb 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '05 Feb 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-02-08T06:49:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '90d71b8d-83ba-4dbb-917a-87b0b762d614' | System | 08 Feb 2021 12:49:43 |
| User entered 'No (N)' | System | 08 Feb 2021 12:49:43 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-02-08T06:49:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '90d71b8d-83ba-4dbb-917a-87b0b762d614' | System | 08 Feb 2021 12:49:43 |
| User entered 'No (N)' | System | 08 Feb 2021 12:49:43 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-02-08T06:49:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '90d71b8d-83ba-4dbb-917a-87b0b762d614' | System | 08 Feb 2021 12:49:43 |
| User entered '08 Feb 2021 06:49:40' | System | 08 Feb 2021 12:49:43 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '08 Feb 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '12 Feb 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-02-15T17:10:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '91ae10d5-a0e9-401f-bff9-1c597e349287' | System | 15 Feb 2021 23:14:40 |
| User entered 'No (N)' | System | 15 Feb 2021 23:14:40 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-02-15T17:10:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '91ae10d5-a0e9-401f-bff9-1c597e349287' | System | 15 Feb 2021 23:14:40 |
| User entered 'No (N)' | System | 15 Feb 2021 23:14:40 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-02-15T17:10:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '91ae10d5-a0e9-401f-bff9-1c597e349287' | System | 15 Feb 2021 23:14:40 |
| User entered '15 Feb 2021 17:10:06' | System | 15 Feb 2021 23:14:40 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '15 Feb 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '19 Feb 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-02-22T20:08:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '34bceec9-4989-429b-b0d1-a735443e13a3' | System | 23 Feb 2021 02:17:01 |
| User entered 'No (N)' | System | 23 Feb 2021 02:17:01 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-02-22T20:08:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '34bceec9-4989-429b-b0d1-a735443e13a3' | System | 23 Feb 2021 02:17:01 |
| User entered 'No (N)' | System | 23 Feb 2021 02:17:01 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-02-22T20:08:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '34bceec9-4989-429b-b0d1-a735443e13a3' | System | 23 Feb 2021 02:17:01 |
| User entered '22 Feb 2021 20:08:43' | System | 23 Feb 2021 02:17:01 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '22 Feb 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '26 Feb 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-03-02T00:32:07-06:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2b334dae-d2d9-4a11-98c4-fff05ae504bf' User entered 'No (N)' | System | 02 Mar 2021 06:32:16 |
| | System | 02 Mar 2021 06:32:16 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-03-02T00:32:13-06:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2b334dae-d2d9-4a11-98c4-fff05ae504bf' User entered 'No (N)' | System | 02 Mar 2021 06:32:16 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-03-02T00:32:15-06:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2b334dae-d2d9-4a11-98c4-fff05ae504bf' User entered '02 Mar 2021 00:32:15' | System | 02 Mar 2021 06:32:16 |
| | System | 02 Mar 2021 06:32:16 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '01 Mar 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '05 Mar 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-03-08T07:01:47-06:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '79d0e1d0-47d8-4b0d-a350-5e143adc4f9e' | System | 08 Mar 2021 13:01:55 |
| User entered 'No (N)' | System | 08 Mar 2021 13:01:55 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-03-08T07:01:50-06:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '79d0e1d0-47d8-4b0d-a350-5e143adc4f9e' | System | 08 Mar 2021 13:01:55 |
| User entered 'No (N)' | System | 08 Mar 2021 13:01:55 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-03-08T07:01:52-06:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '79d0e1d0-47d8-4b0d-a350-5e143adc4f9e' User entered '08 Mar 2021 07:01:52' | System | 08 Mar 2021 13:01:55 |
| | System | 08 Mar 2021 13:01:55 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '08 Mar 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '12 Mar 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-03-16T09:15:40-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0c29f8eb-3380-4aa5-b312-8f96202aefaa' | System | 16 Mar 2021 14:15:52 |
| User entered 'No (N)' | System | 16 Mar 2021 14:15:52 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-03-16T09:15:43-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0c29f8eb-3380-4aa5-b312-8f96202aefaa' | System | 16 Mar 2021 14:15:52 |
| User entered 'No (N)' | System | 16 Mar 2021 14:15:52 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-03-16T09:15:45-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0c29f8eb-3380-4aa5-b312-8f96202aefaa' | System | 16 Mar 2021 14:15:52 |
| User entered '16 Mar 2021 09:15:45' | System | 16 Mar 2021 14:15:52 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '15 Mar 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '19 Mar 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-03-22T23:03:07-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0796d060-fd8f-49b7-b611-843b562db567' | System | 23 Mar 2021 04:04:00 |
| User entered 'No (N)' | System | 23 Mar 2021 04:04:00 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-03-22T23:03:10-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0796d060-fd8f-49b7-b611-843b562db567' | System | 23 Mar 2021 04:04:00 |
| User entered 'No (N)' | System | 23 Mar 2021 04:04:00 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-03-22T23:03:12-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0796d060-fd8f-49b7-b611-843b562db567' | System | 23 Mar 2021 04:04:00 |
| User entered '22 Mar 2021 23:03:12' | System | 23 Mar 2021 04:04:00 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '22 Mar 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '26 Mar 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-03-29T07:21:19-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'fc6ab858-d43f-4b7f-a11f-baf9f418ce19' | System | 29 Mar 2021 12:21:26 |
| User entered 'No (N)' | System | 29 Mar 2021 12:21:26 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-03-29T07:21:21-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'fc6ab858-d43f-4b7f-a11f-baf9f418ce19' | System | 29 Mar 2021 12:21:26 |
| User entered 'No (N)' | System | 29 Mar 2021 12:21:26 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-03-29T07:21:23-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'fc6ab858-d43f-4b7f-a11f-baf9f418ce19' | System | 29 Mar 2021 12:21:26 |
| User entered '29 Mar 2021 07:21:23' | System | 29 Mar 2021 12:21:26 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '29 Mar 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '02 Apr 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-04-06T10:23:28-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '671912cf-6751-45f0-b169-4c8ba744fc6c' | System | 06 Apr 2021 15:23:38 |
| User entered 'No (N)' | System | 06 Apr 2021 15:23:38 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-04-06T10:23:30-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '671912cf-6751-45f0-b169-4c8ba744fc6c' | System | 06 Apr 2021 15:23:38 |
| User entered 'No (N)' | System | 06 Apr 2021 15:23:38 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-04-06T10:23:33-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '671912cf-6751-45f0-b169-4c8ba744fc6c' User entered '06 Apr 2021 10:23:33' | System | 06 Apr 2021 15:23:38 |
| | System | 06 Apr 2021 15:23:38 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '05 Apr 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '09 Apr 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-04-12T17:26:37-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b572fdbbc-c4a2-4017-9065-425501aca435' | System | 12 Apr 2021 22:26:46 |
| User entered 'No (N)' | System | 12 Apr 2021 22:26:46 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-04-12T17:26:42-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b572fdbbc-c4a2-4017-9065-425501aca435' | System | 12 Apr 2021 22:26:46 |
| User entered 'No (N)' | System | 12 Apr 2021 22:26:46 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-04-12T17:26:45-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b572fdbc-c4a2-4017-9065-425501aca435' | System | 12 Apr 2021 22:26:46 |
| User entered '12 Apr 2021 17:26:45' | System | 12 Apr 2021 22:26:46 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '12 Apr 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '16 Apr 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-04-19T06:23:34-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2dcce69b-5582-4165-a589-c9f2d9beb96c' User entered 'No (N)' | System | 19 Apr 2021 11:23:45 |
| | System | 19 Apr 2021 11:23:45 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-04-19T06:23:40-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2dcce69b-5582-4165-a589-c9f2d9beb96c' | System | 19 Apr 2021 11:23:45 |
| User entered 'No (N)' | System | 19 Apr 2021 11:23:45 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-04-19T06:23:43-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2dcce69b-5582-4165-a589-c9f2d9beb96c' User entered '19 Apr 2021 06:23:43' | System | 19 Apr 2021 11:23:45 |
| | System | 19 Apr 2021 11:23:45 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '19 Apr 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '23 Apr 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-04-26T06:31:56-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '899fde38-d664-409d-83f3-9cb3417fde6f' User entered 'No (N)' | System | 26 Apr 2021 11:32:11 |
| | System | 26 Apr 2021 11:32:11 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-04-26T06:32:04-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '899fde38-d664-409d-83f3-9cb3417fde6f' User entered 'No (N)' | System | 26 Apr 2021 11:32:11 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-04-26T06:32:08-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '899fde38-d664-409d-83f3-9cb3417fde6f' User entered '26 Apr 2021 06:32:08' | System | 26 Apr 2021 11:32:11 |
| | System | 26 Apr 2021 11:32:11 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '26 Apr 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '30 Apr 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[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 (e45941109fd6dbd5)', Time: '2021-05-03T07:18:42-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '55808d5c-3aae-45a9-bc5a-420dd2eb43d7' | System | 03 May 2021 12:18:48 |
| User entered 'No (N)' | System | 03 May 2021 12:18:48 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2021-05-03T07:18:46-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '55808d5c-3aae-45a9-bc5a-420dd2eb43d7' | System | 03 May 2021 12:18:48 |
| User entered 'No (N)' | System | 03 May 2021 12:18:48 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-05-03T07:18:48-05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '55808d5c-3aae-45a9-bc5a-420dd2eb43d7' User entered '03 May 2021 07:18:48' | System | 03 May 2021 12:18:48 |
| | System | 03 May 2021 12:18:48 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '03 May 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '07 May 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '10 May 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '14 May 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '17 May 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '21 May 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '24 May 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '28 May 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '31 May 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '04 Jun 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '07 Jun 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '11 Jun 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '14 Jun 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '18 Jun 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '21 Jun 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '25 Jun 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '28 Jun 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '02 Jul 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '05 Jul 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '09 Jul 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '12 Jul 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '16 Jul 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '19 Jul 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '23 Jul 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '26 Jul 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '30 Jul 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '02 Aug 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '06 Aug 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '09 Aug 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '13 Aug 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '16 Aug 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '20 Aug 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '23 Aug 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '27 Aug 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '30 Aug 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '03 Sep 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '06 Sep 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '10 Sep 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '13 Sep 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '17 Sep 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '20 Sep 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '24 Sep 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '27 Sep 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '01 Oct 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '04 Oct 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '08 Oct 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '11 Oct 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '15 Oct 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '18 Oct 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '22 Oct 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '25 Oct 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '29 Oct 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '01 Nov 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '05 Nov 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '08 Nov 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '12 Nov 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '15 Nov 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '19 Nov 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '22 Nov 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '26 Nov 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '29 Nov 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '03 Dec 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '06 Dec 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '10 Dec 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '13 Dec 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '17 Dec 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '20 Dec 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '24 Dec 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '27 Dec 2021 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '31 Dec 2021 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '03 Jan 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '07 Jan 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '10 Jan 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '14 Jan 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '17 Jan 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '21 Jan 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '24 Jan 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '28 Jan 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '31 Jan 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '04 Feb 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '07 Feb 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '11 Feb 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '14 Feb 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '18 Feb 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '21 Feb 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '25 Feb 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '28 Feb 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '04 Mar 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '07 Mar 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '11 Mar 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '14 Mar 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '18 Mar 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '21 Mar 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '25 Mar 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '28 Mar 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '01 Apr 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '04 Apr 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '08 Apr 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '11 Apr 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '15 Apr 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '18 Apr 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '22 Apr 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '25 Apr 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '29 Apr 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '02 May 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '06 May 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '09 May 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '13 May 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '16 May 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '20 May 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '23 May 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '27 May 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '30 May 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '03 Jun 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '06 Jun 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '10 Jun 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '13 Jun 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '17 Jun 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '20 Jun 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '24 Jun 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '27 Jun 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '01 Jul 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '04 Jul 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '08 Jul 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '11 Jul 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '15 Jul 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '18 Jul 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '22 Jul 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '25 Jul 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '29 Jul 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '01 Aug 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '05 Aug 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '08 Aug 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '12 Aug 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '15 Aug 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '19 Aug 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '22 Aug 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '26 Aug 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '29 Aug 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '02 Sep 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '05 Sep 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '09 Sep 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '12 Sep 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '16 Sep 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '19 Sep 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '23 Sep 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '26 Sep 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '30 Sep 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '03 Oct 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '07 Oct 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '10 Oct 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '14 Oct 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '17 Oct 2022 00:01' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:09

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 08:38:42 |
| Amendment Manager: User entered '21 Oct 2022 23:59' | System | 19 Nov 2020 08:38:42 |

US3272169

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:21:09

[Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-03-02T00:32:23-06:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '22e8ffe1-42c6-4adf-93de-7c7ee05e6a88' | System | 02 Mar 2021 06:32:51 |
| User entered 'Yes (Y)' | System | 02 Mar 2021 06:32:51 |

US3272169

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:21:09

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-03-02T00:32:37-06:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '22e8ffe1-42c6-4adf-93de-7c7ee05e6a88' | System | 02 Mar 2021 06:32:51 |
| User entered 'No (N)' | System | 02 Mar 2021 06:32:51 |

US3272169

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:21:09

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:08:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2021-03-02T00:32:47-06:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '22e8ffe1-42c6-4adf-93de-7c7ee05e6a88' | System | 02 Mar 2021 06:32:51 |
| User entered '02 Mar 2021 00:32:47' | System | 02 Mar 2021 06:32:51 |

US3272169

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:56:00 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Nov 2020 14:28:08 |

US3272169

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:56:00 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '13 Nov 2020' | (b) (4), (b) (6) | 13 Nov 2020 14:28:08 |

US3272169

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:56:00 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 13 Nov 2020 14:28:08 |

US3272169

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:56:00 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 14:28:08 |

US3272169

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:56:00 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Nov 2020 14:57:13 |

US3272169

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:56:00 |
| User entered 'I' | System | 13 Nov 2020 14:57:13 |

US3272169

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 18:25:31 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Dec 2020 20:56:52 |

US3272169

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 18:25:31 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '15 Dec 2020' | (b) (4), (b) (6) | 15 Dec 2020 20:56:52 |

US3272169

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 18:25:31 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 15 Dec 2020 20:56:52 |

US3272169

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 18:25:31 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 15 Dec 2020 20:56:52 |

US3272169

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 18:25:31 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Dec 2020 20:56:56 |

US3272169

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 18:25:31 |
| User entered 'I' | System | 15 Dec 2020 20:56:56 |

US3272169

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:38:45 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 18 Jan 2021 14:52:26 |

US3272169

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:38:45 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '13 Jan 2021' | (b) (4), (b) (6) | 18 Jan 2021 14:52:26 |

US3272169

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:38:45 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 18 Jan 2021 14:52:26 |

US3272169

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:38:45 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 18 Jan 2021 14:52:26 |

US3272169

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:38:45 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 18 Jan 2021 14:52:31 |

US3272169

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:38:45 |
| User entered 'I' | System | 18 Jan 2021 14:52:31 |

US3272169

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:47:05 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Feb 2021 16:43:35 |

US3272169

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:47:05 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '11 Feb 2021' | (b) (4), (b) (6) | 17 Feb 2021 16:43:35 |

US3272169

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:47:05 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 17 Feb 2021 16:43:35 |

US3272169

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:09

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:47:05 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 17 Feb 2021 16:43:35 |

US3272169

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:47:05 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Feb 2021 16:43:26 |

US3272169

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:47:05 |
| User entered 'I' | System | 17 Feb 2021 16:43:26 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | Ashley Bell (b) (4) | 30 Mar 2021 18:36:13 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '23 Mar 2021' | Ashley Bell (b) (4) | 30 Mar 2021 18:36:13 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Clinic (Clinic)' | Ashley Bell (b) (4) | 30 Mar 2021 18:36:13 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User entered 'VISIT4' | System | 30 Mar 2021 18:36:13 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'No (N)' | Ashley Bell (b) (4) | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Ashley Bell (b) (4) | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Ashley Bell (b) (4) | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User entered empty. | System | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Ashley Bell (b) (4) | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Ashley Bell (b) (4) | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Ashley Bell (b) (4) | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Ashley Bell (b) (4) | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User entered empty. | System | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Ashley Bell (b) (4) | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User entered empty. | System | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Ashley Bell (b) (4) | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User entered empty. | System | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Ashley Bell (b) (4) | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User entered empty. | System | 30 Mar 2021 18:36:17 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| | | |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| | | |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:09

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | Ashley Bell (b) (4) | 30 Mar 2021 18:36:28 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:09

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '23 Mar 2021' | Ashley Bell (b) (4) | 30 Mar 2021 18:36:28 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | Ashley Bell (b) (4) | 30 Mar 2021 18:36:46 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '23 Mar 2021' | Ashley Bell (b) (4) | 30 Mar 2021 18:36:46 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '09:15' | Ashley Bell (b) (4) | 30 Mar 2021 18:36:46 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User entered '23 Mar 2021 09:15' | System | 30 Mar 2021 18:36:46 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | Ashley Bell (b) (4) | 30 Mar 2021 18:36:52 |

US3272169

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:09

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:02:30 |
| User entered 'I' | System | 30 Mar 2021 18:36:52 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:21:09

[Date of Contact](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 20 Nov 2020 06:36:12 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. | | 11 Nov 2020 15:16:17 |
| ' answered with 'updated' (Site from DM). | | |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | | 05 Nov 2020 09:31:28 |
| User entered '28 Sep 2020' | Kayla Flege (b) (4) (b) (4) | 28 Sep 2020 21:03:16 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:21:09

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '08:00' | Kayla Flege (b) (4) | 28 Sep 2020 21:03:16 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:21:09

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:40 |
| User entered '28 Sep 2020 08:00' | System | 28 Sep 2020 21:03:16 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:21:09

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' | Kayla Flege (b) (4) | 28 Sep 2020 21:03:16 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:21:09

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | Kayla Flege (b) (4) | 28 Sep 2020 21:03:16 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 1 (Day 1)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '17 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Nov 2020 23:59:07 |
| User entered '28 Sep 2020' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |
| | (b) (4) | |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Per CDM: Response noted however, 'Assessment Not Done' check box should only be "selected" if no assessment is done for ALL symptoms listed. Please review/update Day 1 - Day 11 accordingly. Thank you.' (Site from DM). | (b) (4), (b) (6) | 14 Jan 2021 10:11:05 |
| Query 'Per CDM: Response noted however, 'Assessment Not Done' check box should only be "selected" if no assessment is done for ALL symptoms listed. Please review/update Day 1 - Day 11 accordingly. Thank you.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 15:02:51 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Jan 2021 15:02:40 |
| User opened query 'Per CDM: Response noted however, 'Assessment Not Done' check box should only be "selected" if no assessment is done for ALL symptoms listed. Please review/update Day 1 - Day 11 accordingly. Thank you.' (Site from DM). | (b) (4), (b) (6) | 08 Jan 2021 11:58:51 |
| User closed query 'Per CDM: It appears that 'Assessment Not Done' was checked yet data is present for Day 1 - Day 11. Please review and update accordingly. Thank you.' (Site from DM). | (b) (4), (b) (6) | 08 Jan 2021 11:58:51 |
| Query 'Per CDM: It appears that 'Assessment Not Done' was checked yet data is present for Day 1 - Day 11. Please review and update accordingly. Thank you.' answered with 'assessment was not completed for that day, but information on symptoms was collected for that day' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 22:42:54 |
| User opened query 'Per CDM: It appears that 'Assessment Not Done' was checked yet data is present for Day 1 - Day 11. Please review and update accordingly. Thank you.' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 18:17:17 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Nov 2020 23:59:07 |
| User entered '0' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 30 Nov 2020 23:59:07 |
| User entered '100' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |
| | (b) (4) | |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 30 Nov 2020 23:59:07 |
| User entered '36.8' C | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |
| | (b) (4) | |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Nov 2020 23:59:07 |
| User entered 'None (None)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | Kayla Flege (b) (4) | 28 Sep 2020 21:04:47 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 2 (Day 2)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '18 Sep 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Jan 2021 15:02:40 |
| User entered '1' | | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 3 (Day 3)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '19 Sep 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Jan 2021 15:02:40 |
| User entered '1' | | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 4 (Day 4)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '20 Sep 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Jan 2021 15:02:40 |
| User entered '1' | | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 5 (Day 5)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '21 Sep 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Jan 2021 15:02:40 |
| User entered '1' | | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 6 (Day 6)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '22 Sep 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Jan 2021 15:02:40 |
| User entered '1' | | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 7 (Day 7)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '23 Sep 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Jan 2021 15:02:40 |
| User entered '1' | | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 8 (Day 8)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Jan 2021 15:02:40 |
| User entered '1' | | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 9 (Day 9)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '25 Sep 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Jan 2021 15:02:40 |
| User entered '1' | | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 10 (Day 10)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '26 Sep 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Jan 2021 15:02:40 |
| User entered '1' | | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:08:15 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 11 (Day 11)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '27 Nov 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Jan 2021 15:02:40 |
| User entered '1' reason for change: Data Entry Error | | 01 Dec 2020 00:16:47 |
| User entered '0' | | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 12 (Day 12)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '28 Nov 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '100' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '36.8' C | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:10:00 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 13 (Day 13)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '29 Sep 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '100' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '99.9' F | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Severe (Severe)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:11:17 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 14 (Day 14)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '30 Sep 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '100' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '98.7' F | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:12:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 15 (Day 15)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '1 Oct 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '97' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '99.8' F | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:13:37 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 16 (Day 16)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '2 Oct 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '98' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '98.6' F | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:14:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 17 (Day 17)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '3 Oct 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '98' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '98.6' F | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:15:39 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Day 18 (Day 18)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '4 Oct 2020' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '99' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User entered '%' | System | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '98.6' F | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:21:09

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'None (None)' | (b) (4), (b) (6) | 01 Dec 2020 00:16:26 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:21:09

[Date of Visit](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Per GCL Lab Reconciliation: Swab Sample dated 27Sep2020 is recorded under Illness visit in EDC, however a serum sample is also reported under Illness visit dated 28Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank yo' (Site from DM). | (b) (4), (b) (6) | 25 Nov 2020 21:10:12 |
| Query 'Per GCL Lab Reconciliation: Swab Sample dated 27Sep2020 is recorded under Illness visit in EDC, however a serum sample is also reported under Illness visit dated 28Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank yo' answered with 'date is correct' (Site from DM). | (b) (4), (b) (6) | 28 Oct 2020 15:38:09 |
| User opened query 'Per GCL Lab Reconciliation: Swab Sample dated 27Sep2020 is recorded under Illness visit in EDC, however a serum sample is also reported under Illness visit dated 28Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank yo' (Site from DM). | (b) (4), (b) (6) | 25 Oct 2020 22:27:11 |
| Query 'Per GCL Lab Reconciliation: Swab Sample dated 28Sep2020 is recorded under Illness visit in EDC, however a saliva sample is also reported under Illness visit dated 30Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you. | (b) (4), (b) (6) | 25 Oct 2020 22:25:32 |
| ' canceled (Site from DM). | (b) (4), (b) (6) | 25 Oct 2020 20:57:57 |
| User opened query 'Per GCL Lab Reconciliation: Swab Sample dated 28Sep2020 is recorded under Illness visit in EDC, however a saliva sample is also reported under Illness visit dated 30Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you. | (b) (4), (b) (6) | 25 Oct 2020 20:57:57 |
| ' (Site from DM). | (b) (4), (b) (6) | 25 Oct 2020 20:57:57 |
| User entered '28 Sep 2020' | Kayla Flege (b) (4) | 28 Sep 2020 21:03:35 |
| | (b) (4) | |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:21:09

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 28 SEP 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 20 Nov 2020 08:30:39 |
| Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 28 SEP 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 15:16:06 |
| User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 28 SEP 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 09 Nov 2020 08:54:15 |
| User entered 'Yes (Y)' | Kayla Flege (b) (4) | 28 Sep 2020 21:03:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:21:09

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 28 Sep 2020 21:03:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:21:09

[Date of Test](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '28 Sep 2020' | Kayla Flege (b) (4) | 28 Sep 2020 21:03:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:21:09

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | Kayla Flege (b) (4) | 28 Sep 2020 21:03:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:21:09

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Kayla Flege (b) (4) | 28 Sep 2020 21:03:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:21:09

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 28 Sep 2020 21:03:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:21:09

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Kayla Flege (b) (4) | 28 Sep 2020 21:03:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:21:09

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | Kayla Flege (b) (4) | 28 Sep 2020 21:03:35 |

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:21:09

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:42:53 |
| User entered '0' | System | 28 Sep 2020 21:03:35 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:21:09

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User accepted default value 'Day 3 (Day 3)' | | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:21:09

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:21:09

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '30 Sep 2020' | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:21:09

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD. Please provide the Accession number and tracking number with shipping date in the response as the information is needed for the tracking the sample in PPD' (Site from DM). | | 23 Feb 2021 12:50:07 |
| Query 'Per GCL Lab Reconciliation Requery: Saliva Per response, since the sample is still missing in PPD Please provide the Accession number and tracking number with shipping date in the response as the information is needed for the tracking the sample in PPD' answered with 'sample was shipped' (Site from DM). | | 03 Feb 2021 21:39:17 |
| User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD. Please provide the Accession number and tracking number with shipping date in the response as the information is needed for the tracking the sample in PPD' (Site from DM). | | 22 Jan 2021 09:59:53 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM). | (b) (4), (b) (6) | 22 Jan 2021 09:59:53 |
| Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'sample shipped' (Site from DM). | | 13 Jan 2021 14:21:20 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM). | | 11 Jan 2021 06:49:41 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:21:09

[Visit](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 14 Dec 2020 09:31:15 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'sample has been shipped. no samples at site for this number' (Site from DM). | Kayla Flege (b) (4) | 09 Dec 2020 17:36:06 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4) | |
| User accepted default value 'Day 5 (Day 5)' | (b) (4), (b) (6) | 04 Dec 2020 10:57:57 |
| | | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:21:09

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:21:09

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 02OCT2020 for Day 5 in EDC, however 02OCT2020 is reported under Day 5((Accession # 1F653163602) in PPD Central lab. Please confirm date of collection for Day 5 and update EDC or PPD Central lab.' (Site from DM). | (b) (4), (b) (6) | 01 Mar 2021 12:10:36 |
| Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 02OCT2020 for Day 5 in EDC, however 02OCT2020 is reported under Day 5((Accession # 1F653163602) in PPD Central lab. Please confirm date of collection for Day 5 and update EDC or PPD Central lab.' answered with '02OCT2020 date is correct. Am I not seeing the differences in the dates? ' (Site from DM). | Whitney West (b) (4) | 25 Feb 2021 15:24:51 |
| User entered '02 Oct 2020' reason for change: Data Entry Error | Whitney West (b) (4) | 25 Feb 2021 15:23:43 |
| User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 02OCT2020 for Day 5 in EDC, however 02OCT2020 is reported under Day 5((Accession # 1F653163602) in PPD Central lab. Please confirm date of collection for Day 5 and update EDC or PPD Central lab.' (Site from DM). | (b) (4), (b) (6) | 23 Feb 2021 15:00:22 |
| User entered '2 Oct 2020' | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:21:09

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User accepted default value 'Day 7 (Day 7)' | | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:21:09

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:21:09

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:21:09

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User accepted default value 'Day 9 (Day 9)' | | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:21:09

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:21:09

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:21:09

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User accepted default value 'Day 14 (Day 14)' | | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:21:09

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:21:09

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:21:09

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User accepted default value 'Day 21 (Day 21)' | | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:21:09

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:21:09

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:21:09

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User accepted default value 'Day 28 (Day 28)' | | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:21:09

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:21:09

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 11 Nov 2020 15:20:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:52 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Nov 2020 15:16:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:52 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '28 Sep 2020' | (b) (4), (b) (6) | 11 Nov 2020 15:16:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:52 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 11 Nov 2020 15:16:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:52 |
| User entered 'SICKD1' | System | 11 Nov 2020 15:16:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '28 Sep 2020' | (b) (4), (b) (6) | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '15:18' | (b) (4), (b) (6) | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User entered '28 Sep 2020 15:18' | System | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '175' cm | (b) (4), (b) (6) | 11 Nov 2020 15:17:43 |
| DataPoint set to visible. | System | 11 Nov 2020 15:16:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Weight \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '135.6' lb reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Dec 2020 16:07:44 |
| User entered '135.6' kg | (b) (4), (b) (6) | 11 Nov 2020 15:17:43 |
| DataPoint set to visible. | System | 11 Nov 2020 15:16:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '36.8' C | (b) (4), (b) (6) | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered empty. | (b) (4), (b) (6) | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '76' | (b) (4), (b) (6) | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User entered 'bpm' | System | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '17' | (b) (4), (b) (6) | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User entered 'breaths/min' | System | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '95' | (b) (4), (b) (6) | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User entered 'mmHg' | System | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '66' | (b) (4), (b) (6) | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| User entered 'mmHg' | System | 11 Nov 2020 15:17:43 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| | | |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:09

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:56 |
| | | |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:09

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:59 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Nov 2020 15:18:06 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:09

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:53:59 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '28 Sep 2020' | (b) (4), (b) (6) | 11 Nov 2020 15:18:06 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:21:09

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:03 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Nov 2020 15:18:22 |

US3272169

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:21:09

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:54:03 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '28 Sep 2020' | (b) (4), (b) (6) | 11 Nov 2020 15:18:22 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | Andrea Clement (b) (4) | 01 Mar 2021 22:20:17 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '27 Feb 2021' | Andrea Clement (b) (4) | 01 Mar 2021 22:20:17 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Clinic (Clinic)' | Andrea Clement (b) (4) | 01 Mar 2021 22:20:17 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:09

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User entered 'UNBLND_DECIDE' | System | 01 Mar 2021 22:20:17 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:21:09

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '27 Feb 2021' | Andrea Clement (b) (4) | 01 Mar 2021 22:21:29 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:21:09

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '0' | Ashley Bell (b) (4) | 30 Mar 2021 18:37:05 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 12:48:39 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:21:09

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | Andrea Clement (b) (4) | 01 Mar 2021 22:21:29 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:21:09

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | Ashley Bell (b) (4) | 30 Mar 2021 18:37:05 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 12:48:39 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:21:09

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '27 Feb 2021' | Andrea Clement (b) (4) | 01 Mar 2021 22:21:29 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:21:09

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'mRNA-1273 (mRNA-1273)' | Andrea Clement (b) (4) | 01 Mar 2021 22:21:29 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:21:09

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'mRNA-1273 (mRNA-1273)' | Andrea Clement (b) (4) | 01 Mar 2021 22:21:29 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:21:09

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'mRNA-1273 (mRNA-1273)' | Andrea Clement (b) (4) | 01 Mar 2021 22:21:29 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:21:09

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'No (N)' | Andrea Clement (b) (4) | 01 Mar 2021 22:21:29 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:21:09

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User entered empty. | System | 01 Mar 2021 22:21:29 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:21:09

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User entered empty. | System | 01 Mar 2021 22:21:29 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | Andrea Clement (b) (4) | 01 Mar 2021 22:21:50 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '27 Feb 2021' | Andrea Clement (b) (4) | 01 Mar 2021 22:21:50 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '13:15' | Andrea Clement (b) (4) | 01 Mar 2021 22:21:50 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:09

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User entered '27 Feb 2021 13:15' | System | 01 Mar 2021 22:21:50 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:21:09

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'Yes (Y)' | Andrea Clement (b) (4) | 01 Mar 2021 22:22:10 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:21:09

[Collection date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '27 Feb 2021' | Andrea Clement (b) (4) | 01 Mar 2021 22:22:10 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:21:09

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '13:16' | Andrea Clement (b) (4) | 01 Mar 2021 22:22:10 |

US3272169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:21:09

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:49:29 |
| User entered '27 Feb 2021 13:16' | System | 01 Mar 2021 22:22:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:21:09

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 05:00:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 27 Nov 2020 16:27:00 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Kayla Flege (b) (4) | 06 Oct 2020 20:46:49 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:48:06 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastroenteritis, LLT: Gastroenteritis - version MedDRA\\23.0. | Coder Import (b) (4) | 06 Oct 2020 20:49:27 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 06 Oct 2020 20:49:27 |
| Data point term sent to Coder | System | 06 Oct 2020 20:47:55 |
| User entered 'Gastroenteritis' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '20 Aug 2020' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User entered empty. | System | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 14 Apr 2021 19:02:31 |
| Signature has been broken. | (b) (4), (b) (6) | 12 Apr 2021 19:01:35 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 19:01:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM). | (b) (4), (b) (6) | 02 Dec 2020 13:22:43 |
| Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'still ongoing' (Site from DM). | (b) (4), (b) (6) | 25 Nov 2020 17:11:45 |
| User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM). | (b) (4), (b) (6) | 25 Nov 2020 07:40:16 |
| User entered 'Yes (Y)' | Kayla Flege (b) (4) (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 14 Apr 2021 19:02:31 |
| Signature has been broken. | (b) (4), (b) (6) | 12 Apr 2021 19:01:35 |
| User entered '31 Aug 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 19:01:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User entered empty. | System | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'None (NONE)' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[None](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 17 Feb 2021 22:12:03 |
| User entered '1' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |
| | (b) (4) | |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 17 Feb 2021 22:12:03 |
| User entered '0' | Kayla Flege (b) (4) (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 14 Apr 2021 19:02:31 |
| Signature has been broken. | (b) (4), (b) (6) | 12 Apr 2021 19:01:35 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 19:01:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Kayla Flege (b) (4) (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User entered '0' | System | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| User entered 'I' | System | 06 Oct 2020 20:47:28 |

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:46 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Mar 2021 15:05:43 |
| User entered empty. | | 02 Dec 2020 19:16:54 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per MM, this subject presented with fatigue, headache (onsets 16Sep2020) and generalzied muscle aches (onset 17Sep2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM). | (b) (4), (b) (6) | 02 Dec 2020 13:42:06 |
| Query 'Per MM, this subject presented with fatigue, headache (onsets 16Sep2020) and generalzied muscle aches (onset 17Sep2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 01 Dec 2020 00:22:24 |
| User opened query 'Per MM, this subject presented with fatigue, headache (onsets 16Sep2020) and generalzied muscle aches (onset 17Sep2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 20:42:29 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0. | Coder Import (b) (4) | 06 Oct 2020 20:51:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 06 Oct 2020 20:51:17 |
| Data point term sent to Coder | System | 06 Oct 2020 20:50:00 |
| User entered 'Fatigue' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 20:46:10 |
| Query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) | 02 Nov 2020 19:51:45 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | 02 Nov 2020 19:51:20 |
| User opened query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM). | (b) (4), (b) (6) | 01 Nov 2020 06:40:18 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety). | (b) (4), (b) (6) | 10 Dec 2020 03:27:20 |
| Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'ok' (Site from Safety). | Kayla Flege (b) (4) | 09 Dec 2020 15:58:20 |
| User entered 'No (N)' reason for change: Data Entry Error | Kayla Flege (b) (4) | 09 Dec 2020 15:58:10 |
| User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety). | (b) (4), (b) (6) | 02 Dec 2020 19:16:43 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 01 Dec 2020 00:22:18 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: AE, Fatigue with start date (16SEP2020) does not match the Diary initial start date of Solicited symptom (Fatigue). Kindly review and update appropriately or provide explanation on dates.' (Site from DM). | (b) (4), (b) (6) | 22 Dec 2020 11:19:40 |
| Query 'Per CDM: AE, Fatigue with start date (16SEP2020) does not match the Diary initial start date of Solicited symptom (Fatigue). Kindly review and update appropriately or provide explanation on dates.' answered with 'yes is does match' (Site from DM). | Kayla Flege (b) (4) | 09 Dec 2020 15:58:58 |
| User opened query 'Per CDM: AE, Fatigue with start date (16SEP2020) does not match the Diary initial start date of Solicited symptom (Fatigue). Kindly review and update appropriately or provide explanation on dates.' (Site from DM). | (b) (4), (b) (6) | 02 Dec 2020 13:45:41 |
| User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 20:46:14 |
| Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) | 02 Nov 2020 19:51:49 |
| User entered '16 Sep 2020' reason for change: Data Entry Error | Kayla Flege (b) (4) | 02 Nov 2020 19:51:38 |
| User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4), (b) (6) | 01 Nov 2020 06:40:25 |
| User entered '17 Sep 2020' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 15:07:43 |
| Query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' answered with 'data not collected' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 15:14:26 |
| User opened query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 16:23:05 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 03 Nov 2020 19:12:48 |
| Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System). | Kayla Flege (b) (4) | 06 Oct 2020 20:49:12 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 20:49:03 |
| User entered empty. | System | 06 Oct 2020 20:49:03 |
| | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User entered empty. | System | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 06 Oct 2020 20:49:29 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System | 06 Oct 2020 20:49:29 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 06 Oct 2020 20:49:03 |
| User entered '2 Oct 2020' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 03 Nov 2020 19:12:50 |
| Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System). | Kayla Flege (b) (4) | 06 Oct 2020 20:49:23 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 06 Oct 2020 20:49:03 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User entered empty. | System | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'None (NONE)' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Kayla Flege (b) (4) | 06 Oct 2020 20:49:29 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User entered '0' | System | 06 Oct 2020 20:49:03 |

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| User entered '0' | System | 06 Oct 2020 20:49:03 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:54 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: Please review and update AE term to reflect if MUSCLE ACHES is Generalized or found on a specific body location. Please reconcile with the ConMed eCRF so there is an appropriate match' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 15:08:22 |
| User closed query 'Per MM, please confirm if this is symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 15:08:21 |
| Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'yes subject came in for illness visit and was negative for covid' (Site from DM). | (b) (4), (b) (6) | 20 Nov 2020 22:04:14 |
| User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM). | (b) (4), (b) (6) | 12 Nov 2020 22:57:26 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0. | Coder Import (b) (4) | 30 Oct 2020 18:55:57 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 30 Oct 2020 18:55:57 |
| Data point term sent to Coder | System | 30 Oct 2020 18:55:13 |
| Query 'Per CDM: Please review and update AE term to reflect if MUSCLE ACHES is Generalized or found on a specific body location. Please reconcile with the ConMed eCRF so there is an appropriate match' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 18:55:05 |
| Coding entries removed. | (b) (4), (b) (6) | 30 Oct 2020 18:54:57 |
| User entered 'generalized MUSCLE ACHES' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Oct 2020 18:54:57 |
| User opened query 'Per CDM: Please review and update AE term to reflect if MUSCLE ACHES is Generalized or found on a specific body location. Please reconcile with the ConMed eCRF so there is an appropriate match' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 10:16:13 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0. | Coder Import (b) (4) | 06 Oct 2020 20:55:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 06 Oct 2020 20:55:24 |
| Data point term sent to Coder | System | 06 Oct 2020 20:54:09 |
| User entered 'Muscle Aches' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 15:08:35 |
| Query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) | 02 Nov 2020 19:52:28 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | 02 Nov 2020 19:52:23 |
| User opened query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM). | (b) (4), (b) (6) | 01 Nov 2020 06:40:40 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '17 Sep 2020' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 15:08:43 |
| Query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' answered with 'data not collected' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 15:14:46 |
| User opened query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 16:26:01 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 30 Oct 2020 10:16:35 |
| Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System). | Kayla Flege (b) (4) | 06 Oct 2020 20:54:06 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 20:53:56 |
| User entered empty. | System | 06 Oct 2020 20:53:56 |
| | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User entered empty. | System | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System | 06 Oct 2020 20:54:13 |
| User entered 'No (N)' reason for change: Data Entry Error | Kayla Flege (b) (4) | 06 Oct 2020 20:54:13 |
| User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System | 06 Oct 2020 20:53:56 |
| User entered 'Yes (Y)' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '3 Oct 2020' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 30 Oct 2020 10:16:38 |
| Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System). | Kayla Flege (b) (4) | 06 Oct 2020 20:54:18 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 06 Oct 2020 20:54:13 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User entered empty. | System | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'None (NONE)' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User entered '0' | System | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| User entered '0' | System | 06 Oct 2020 20:53:56 |

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:01 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0. | Coder Import (b) (4) | 06 Oct 2020 21:08:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 06 Oct 2020 21:08:18 |
| Data point term sent to Coder | System | 06 Oct 2020 21:07:27 |
| User entered 'Headache' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 20:51:19 |
| Query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) | 02 Nov 2020 19:53:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Kayla Flege (b) (4) | 02 Nov 2020 19:52:46 |
| User opened query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM). | (b) (4), (b) (6) | 01 Nov 2020 06:41:00 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety). | (b) (4), (b) (6) | 07 Oct 2020 18:29:34 |
| Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'UPDATD' (Site from Safety). | Kayla Flege (b) (4) | 07 Oct 2020 18:29:21 |
| User entered 'No (N)' reason for change: Data Entry Error | Kayla Flege (b) (4) | 07 Oct 2020 18:29:12 |
| User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety). | (b) (4), (b) (6) | 07 Oct 2020 14:20:29 |
| User entered 'Yes (Y)' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query ' Per CDM: AE, Headache with start date (16SEP2020) does not match the Diary initial start date of Solicited symptom (Headache). Kindly review and update appropriately or provide explanation on dates' (Site from DM). | (b) (4), (b) (6) | 22 Dec 2020 11:20:13 |
| Query ' Per CDM: AE, Headache with start date (16SEP2020) does not match the Diary initial start date of Solicited symptom (Headache). Kindly review and update appropriately or provide explanation on dates' answered with 'yes it does match' (Site from DM). | Kayla Flege (b) (4) | 09 Dec 2020 15:59:17 |
| User opened query ' Per CDM: AE, Headache with start date (16SEP2020) does not match the Diary initial start date of Solicited symptom (Headache). Kindly review and update appropriately or provide explanation on dates' (Site from DM). | (b) (4), (b) (6) | 02 Dec 2020 13:49:10 |
| User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 20:51:24 |
| Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) | 02 Nov 2020 19:53:09 |
| User entered '16 Sep 2020' reason for change: Data Entry Error | Kayla Flege (b) (4) | 02 Nov 2020 19:52:46 |
| User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4), (b) (6) | 01 Nov 2020 06:41:07 |
| User entered '17 Sep 2020' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 15:14:26 |
| Query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' answered with 'data not collected' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 15:15:02 |
| User opened query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 16:26:36 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 30 Oct 2020 10:16:54 |
| Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System). | Kayla Flege (b) (4) | 06 Oct 2020 21:07:08 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 06 Oct 2020 21:06:43 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User entered empty. | System | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '1 Oct 2020' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 30 Oct 2020 10:16:55 |
| Query 'Data is required. Please provide.' answered with 'unknown' (Site from System). | Kayla Flege (b) (4) | 06 Oct 2020 21:07:12 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 06 Oct 2020 21:06:43 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User entered empty. | System | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'None (NONE)' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User entered '0' | System | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| User entered '0' | System | 06 Oct 2020 21:06:43 |

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:37:06 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:31:17 |
| User entered 'USA-US070-2020-mRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |
| User entered 'New' | (b) (4), (b) (6) | 16 Nov 2020 15:31:13 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Anal and rectal conditions NEC, HLT: Anal and rectal disorders NEC, PT: Rectal prolapse, LLT: Rectal prolapse - version MedDRA\\23.0. | Coder Import (b) (4) | 14 Nov 2020 00:02:35 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 14 Nov 2020 00:02:35 |
| Data point term sent to Coder | System | 14 Nov 2020 00:01:29 |
| User entered 'rectal prolapse' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '08 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Dec 2020 23:18:59 |
| User entered '8 Sep 2020' | | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'PV Query: Please confirm the stop date of rectal prolapse. Stop date was reported as 08 Sep 2020, however the subject was hospitalized for the rectal prolapse repair from 19 Oct 2020-24 Oct 2020.' (Site from Safety). | (b) (4), (b) (6) | 16 Dec 2020 16:02:30 |
| Query 'PV Query: Please confirm the stop date of rectal prolapse. Stop date was reported as 08 Sep 2020, however the subject was hospitalized for the rectal prolapse repair from 19 Oct 2020-24 Oct 2020. answered with 'updated' (Site from Safety). | (b) (4), (b) (6) | 15 Dec 2020 23:19:06 |
| User entered '19 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Dec 2020 23:18:59 |
| User entered '08 Sep 2020' reason for change: Data Entry Error | Kayla Flege (b) (4) | 15 Dec 2020 22:36:37 |
| User opened query 'PV Query: Please confirm the stop date of rectal prolapse. Stop date was reported as 08 Sep 2020, however the subject was hospitalized for the rectal prolapse repair from 19 Oct 2020-24 Oct 2020.' (Site from Safety). | (b) (4), (b) (6) | 15 Dec 2020 21:10:22 |
| User closed query 'PV Query: Please confirm the event end date of rectal prolapse (reported as 19 Oct 2020) as the subject was discharged on 24 Oct 2020.' (Site from Safety). | (b) (4), (b) (6) | 24 Nov 2020 13:11:09 |
| Query 'PV Query: Please confirm the event end date of rectal prolapse (reported as 19 Oct 2020) as the subject was discharged on 24 Oct 2020.' answered with 'updated' (Site from Safety). | Kayla Flege (b) (4) | 23 Nov 2020 18:41:42 |
| User entered '8 Sep 2020' reason for change: Data Entry Error | Kayla Flege (b) (4) | 23 Nov 2020 18:41:16 |
| User opened query 'PV Query: Please confirm the event end date of rectal prolapse (reported as 19 Oct 2020) as the subject was discharged on 24 Oct 2020.' (Site from Safety). | (b) (4), (b) (6) | 23 Nov 2020 15:32:51 |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

Severity

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'PV Query: Since the subject was hospitalized for the events, appropriate event severity grade should be grade 4. Please update the event severity as such. If the severity is to remain grade 3, please clarify/explain.' (Site from Safety). | (b) (4), (b) (6) | 24 Nov 2020 13:11:11 |
| Query 'PV Query: Since the subject was hospitalized for the events, appropriate event severity grade should be grade 4. Please update the event severity as such. If the severity is to remain grade 3, please clarify/explain.' answered with 'udpated' (Site from Safety). | Kayla Flege (b) (4) | 23 Nov 2020 18:43:49 |
| User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error | (b) (4) | 23 Nov 2020 18:41:29 |
| User opened query 'PV Query: Since the subject was hospitalized for the events, appropriate event severity grade should be grade 4. Please update the event severity as such. If the severity is to remain grade 3, please clarify/explain.' (Site from Safety). | (b) (4), (b) (6) | 23 Nov 2020 15:33:27 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '1' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| Query 'PV Query: Please confirm the hospitalization dates. Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, however it was reported the subject was re-hospitalized from 05 Nov 2020 to 07 Nov 2020.' canceled (Site from Safety). | (b) (4), (b) (6) | 30 Dec 2020 20:59:19 |
| User opened query 'PV Query: Please confirm the hospitalization dates. Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, however it was reported the subject was re-hospitalized from 05 Nov 2020 to 07 Nov 2020.' (Site from Safety). | | 30 Dec 2020 20:58:42 |
| User entered '19 Oct 2020' | | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '24 Oct 2020' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'PV Query: The event RECTAL PROLAPSE started on 08 Sep 2020, which was after first dose and before the last dose of study drug was administered on 16 Sep 2020. Please consider updating action taken to None for the event of RECTAL PROLAPSE. ' (Site from Safety). | (b) (4), (b) (6) | 10 Dec 2020 18:57:24 |
| Query 'PV Query: The event RECTAL PROLAPSE started on 08 Sep 2020, which was after first dose and before the last dose of study drug was administered on 16 Sep 2020. Please consider updating action taken to None for the event of RECTAL PROLAPSE. ' answered with 'updated' (Site from Safety). | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 16:35:11 |
| User entered 'None (NONE)' reason for change: Data Entry Error | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 16:00:27 |
| User opened query 'PV Query: The event RECTAL PROLAPSE started on 08 Sep 2020, which was after first dose and before the last dose of study drug was administered on 16 Sep 2020. Please consider updating action taken to None for the event of RECTAL PROLAPSE. ' (Site from Safety). | (b) (4), (b) (6) | 03 Dec 2020 18:52:48 |
| User closed query 'PV Query: Please provide the date the subject's last dose of study medication was taken prior to the event. If the subject only received the first dose, please clarify on action taken with IP with regards to next scheduled administration.' (Site from Safety). | (b) (4), (b) (6) | 24 Nov 2020 13:11:14 |
| Query 'PV Query: Please provide the date the subject's last dose of study medication was taken prior to the event. If the subject only received the first dose, please clarify on action taken with IP with regards to next scheduled administration.' answered with '16 SEP 2020' (Site from Safety). | Kayla Flege (b) (4) (b) (4) | 23 Nov 2020 18:44:19 |
| User opened query 'PV Query: Please provide the date the subject's last dose of study medication was taken prior to the event. If the subject only received the first dose, please clarify on action taken with IP with regards to next scheduled administration.' (Site from Safety). | (b) (4), (b) (6) | 23 Nov 2020 15:32:04 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

None

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). | (b) (4), (b) (6) | 17 Dec 2020 10:02:47 |
| Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 16:35:17 |
| User entered '0' reason for change: Data Entry Error | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 16:00:27 |
| User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 05:30:39 |
| User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). | | 23 Nov 2020 18:46:11 |
| User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). | System | 23 Nov 2020 18:44:35 |
| User entered '1' reason for change: Data Entry Error | Kayla Flege (b) (4) (b) (4) | 23 Nov 2020 18:44:35 |
| User entered '0' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

Concomitant Medication

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| Query 'Please provide results of CT scan's done on 04 Nov 2020 and 05 Nov 2020 that were documented in concomitant procedures.' canceled (Site from Safety). | (b) (4), (b) (6) | 26 Feb 2021 23:23:32 |
| User opened query 'Please provide results of CT scan's done on 04 Nov 2020 and 05 Nov 2020 that were documented in concomitant procedures.' (Site from Safety). | (b) (4), (b) (6) | 26 Feb 2021 23:23:25 |
| User entered '1' reason for change: Data Entry Error | Kayla Flege (b) (4) | 09 Dec 2020 16:00:27 |
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 20:12:22 |
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) | 23 Nov 2020 18:45:49 |
| User entered '0' reason for change: Data Entry Error | Kayla Flege (b) (4) | 23 Nov 2020 18:44:35 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 09:52:57 |
| User entered '1' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | 09 Dec 2020 16:00:27 |
| User entered '0' reason for change: Data Entry Error | Kayla Flege (b) (4) | 23 Nov 2020 18:46:11 |
| User closed query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' (Site from DM). | (b) (4) | 23 Nov 2020 15:15:15 |
| Query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 20 Nov 2020 22:04:53 |
| User opened query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 19 Nov 2020 09:42:50 |
| User entered '1' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'PV Query: Please provide results of CT scan's done on 04 Nov 2020 and 05 Nov 2020 that were documented in concomitant procedures. Results not received. Please leave query unanswered until results are sent.' (Site from Safety). | (b) (4), (b) (6) | 11 Mar 2021 15:05:55 |
| Query 'PV Query: Please provide results of CT scan's done on 04 Nov 2020 and 05 Nov 2020 that were documented in concomitant procedures. Results not received. Please leave query unanswered until results are sent.' answered with 'fully repaired' (Site from Safety). | (b) (4), (b) (6) | 10 Mar 2021 15:52:59 |
| User opened query 'PV Query: Please provide results of CT scan's done on 04 Nov 2020 and 05 Nov 2020 that were documented in concomitant procedures. Results not received. Please leave query unanswered until results are sent.' (Site from Safety). | (b) (4), (b) (6) | 04 Mar 2021 17:38:03 |
| User closed query 'PV Query: Please provide results of CT scan's done on 04 Nov 2020 and 05 Nov 2020 that were documented in concomitant procedures.' (Site from Safety). | (b) (4), (b) (6) | 04 Mar 2021 17:38:03 |
| Query 'PV Query: Please provide results of CT scan's done on 04 Nov 2020 and 05 Nov 2020 that were documented in concomitant procedures.' answered with 'will send in ct results' (Site from Safety). | (b) (4), (b) (6) | 03 Mar 2021 21:32:01 |
| User opened query 'PV Query: Please provide results of CT scan's done on 04 Nov 2020 and 05 Nov 2020 that were documented in concomitant procedures.' (Site from Safety). | (b) (4), (b) (6) | 26 Feb 2021 23:24:12 |
| Query 'PV Query: Please confirm the ED date(s). Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, also it was reported subject was seen back at the ED on 04 Nov 2020.' canceled (Site from Safety). | (b) (4), (b) (6) | 30 Dec 2020 20:59:13 |
| User opened query 'PV Query: Please confirm the ED date(s). Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, also it was reported subject was seen back at the ED on 04 Nov 2020.' (Site from Safety). | (b) (4), (b) (6) | 30 Dec 2020 20:58:02 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User closed query 'PV Query: Per follow up query response answer text labs completed are CBC, CMP UA, Procalcitonin, CBC, lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Prottime-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID by PCR. Please provide the diagnostic test results for the above test completed and include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 16 Dec 2020 16:02:44 |
| Query 'PV Query: Per follow up query response answer text labs completed are CBC, CMP, UA, Procalcitonin, CBC, lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Prottime-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID by PCR. Please provide the diagnostic test results for the above test completed and include unit and reference ranges if applicable.' answered with 'data provided' (Site from Safety). | | 15 Dec 2020 23:20:31 |
| User opened query 'PV Query: Per follow up query response answer text labs completed are CBC, CMP UA, Procalcitonin, CBC, lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Prottime-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID by PCR. Please provide the diagnostic test results for the above test completed and include units and reference ranges if applicable.' (Site from Safety). | | 15 Dec 2020 21:09:52 |
| User closed query 'Per DM CLR - RQ: Site's response noted. However, COLONOSCOPY is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM). | (b) (4), (b) (6) | 15 Dec 2020 15:05:40 |
| User closed query 'Per CDM: Response noted, SAE Narrative= Routine Colonoscopy however, there is no Colonoscopy recorded in the Concomitant Procedure eCRF. Kindly review and update accordingly.' (Site from DM). | | 15 Dec 2020 15:05:34 |
| User closed query 'PV Query: Please confirm the event end date of rectal prolapse (reported as 8 SEP 2020) as the subject was discharged on 24 Oct 2020.' (Site from Safety). | | 10 Dec 2020 18:57:44 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User closed query 'PV Query: Per follow up query response answer text labs completed are CBC, CMP, UA, Procalcitonin, CBC, lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Protine-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID by PCR. Please provide the diagnostic test results for the above test completed and include units and reference ranges if applicable. ' (Site from Safety). | (b) (4), (b) (6) | 10 Dec 2020 18:57:39 |
| User closed query 'PV Query: Per follow up ibuprofen was given for indication Rectal Prolapse on 02-SEP-2020 which is before the onset date (08-SEP-2020) of the event Rectal Prolapse. Please confirm onset date of signs and symptoms of event Rectal Prolapse. ' (Site from Safety). | (b) (4), (b) (6) | 10 Dec 2020 18:57:32 |
| Query 'PV Query: Per follow up query response answer text labs completed are CBC, CMP, UA, Procalcitonin, CBC, lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Protine-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID by PCR. Please provide the diagnostic test results for the above test completed and include units and reference ranges if applicable. ' answered with 'Do you want me to fax these labs somewhere or how would you like me to get them to you?' (Site from Safety). | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 17:34:51 |
| Query 'PV Query: Per follow up ibuprofen was given for indication Rectal Prolapse on 02-SEP-2020 which is before the onset date (08-SEP-2020) of the event Rectal Prolapse. Please confirm onset date of signs and symptoms of event Rectal Prolapse. ' answered with 'updated' (Site from Safety). | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 17:32:51 |
| Query 'PV Query: Please confirm the event end date of rectal prolapse (reported as 8 SEP 2020) as the subject was discharged on 24 Oct 2020. ' answered with 'Yes the end date is correct. However she had complications due to the surgery and was then hospitalized again.' (Site from Safety). | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 17:25:32 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Query 'Per DM CLR - RQ: Site's response noted. However, COLONOSCOPY is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) | 09 Dec 2020 16:37:42 |
| Query 'Per CDM: Response noted, SAE Narrative= Routine Colonoscopy however, there is no Colonoscopy recorded in the Concomitant Procedure eCRF. Kindly review and update accordingly.' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) | 09 Dec 2020 16:37:34 |
| User opened query 'Per DM CLR - RQ: Site's response noted. However, COLONOSCOPY is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 05:31:08 |
| User opened query 'PV Query: Please confirm the event end date of rectal prolapse (reported as 8 SEP 2020) as the subject was discharged on 24 Oct 2020. (Site from Safety). | (b) (4), (b) (6) | 03 Dec 2020 18:54:02 |
| User opened query 'PV Query: Per follow up query response answer text labs completed are CBC, CMP, UA, Procalcitonin, CBC, lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Protine-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID by PCR. Please provide the diagnostic test results for the above test completed and include units and reference ranges if applicable. ' (Site from Safety). | (b) (4), (b) (6) | 03 Dec 2020 18:53:41 |
| User opened query 'PV Query: Per follow up ibuprofen was given for indication Rectal Prolapse on 02-SEP-2020 which is before the onset date (08-SEP-2020) of the event Rectal Prolapse. Please confirm onset date of signs and symptoms of event Rectal Prolapse. ' (Site from Safety). | (b) (4), (b) (6) | 03 Dec 2020 18:53:30 |
| User opened query 'Per CDM: Response noted, SAE Narrative= Routine Colonoscopy however, there is no Colonoscopy recorded in the Concomitant Procedure eCRF. Kindly review and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 02 Dec 2020 13:59:05 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User closed query 'Per DM CLR: SAE Narrative = RECEIVED A ROUTINE COLONOSCOPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM). | (b) (4), (b) (6) | 02 Dec 2020 13:59:05 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | | 30 Nov 2020 14:58:17 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | | 30 Nov 2020 14:58:13 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety). | | 25 Nov 2020 17:10:21 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Labs completed are CBC, CMP, UA, Procalcitonin, CBC, Lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Protime-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID-!(by PCR' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 17:09:50 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | | 25 Nov 2020 15:36:29 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'yes covid test was done 04nov2020 and was negative' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 01:18:50 |
| Query 'Per DM CLR: SAE Narrative = RECEIVED A ROUTINE COLONOSCOPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 25 Nov 2020 01:18:03 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 23 Nov 2020 15:33:09 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 23 Nov 2020 15:32:33 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 23 Nov 2020 15:32:19 |
| User opened query 'Per DM CLR: SAE Narrative = RECEIVED A ROUTINE COLONOSCOPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 09:52:47 |
| User entered 'patient disclosed at day 85 phone call on 13nov2020 she had a rectal prolapse that started oct08sep2020 when she received a routine colonoscopy and then had a rectal prolapse repair on 19oct2020 and was inpatient from 19oct2020 to 24oct2020 then had complications and was inpatient again from 05nov2020 to 07nov2020' | (b) (4), (b) (6) | 14 Nov 2020 00:01:01 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 14 Nov 2020 00:01:01 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:31:37 |
| User entered 'USA-US070-2020-mRNA-1273-P301000018' | | 16 Nov 2020 15:31:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Gastrointestinal and hepatobiliary procedural complications, PT: Gastrointestinal procedural complication, LLT: Gastrointestinal procedural complication - version MedDRA\23.0. | Coder Import (b) (4) | 12 Mar 2021 14:31:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 12 Mar 2021 14:31:52 |
| User closed query 'PV Query: Was a final diagnosis for the 'rectal prolapse repair complication' identified? If so, please consider updating the event term to the (specific complication), when known.' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 15:36:56 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Anal and rectal conditions NEC, HLT: Anal and rectal disorders NEC, PT: Rectal prolapse, LLT: Rectal prolapse - version MedDRA\23.0. | Coder Import (b) (4) | 25 Nov 2020 01:32:02 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 25 Nov 2020 01:32:02 |
| Query 'PV Query: Was a final diagnosis for the 'rectal prolapse repair complication' identified? If so, please consider updating the event term to the (specific complication), when known.' answered with 'updated' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 01:13:33 |
| Data point term sent to Coder | System | 25 Nov 2020 01:12:22 |
| Coding entries removed. | (b) (4), (b) (6) | 25 Nov 2020 01:12:16 |
| User entered 'RECTAL PROLAPSE REPAIR COMPLICATION due to constipation' reason for change: Data Entry Error | | 25 Nov 2020 01:12:16 |
| User opened query 'PV Query: Was a final diagnosis for the 'rectal prolapse repair complication' identified? If so, please consider updating the event term to the (specific complication), when known.' (Site from Safety). | (b) (4), (b) (6) | 23 Nov 2020 15:34:02 |

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Folder: Adverse Events

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[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Anal and rectal conditions NEC, HLT: Anal and rectal disorders NEC, PT: Rectal prolapse, LLT: Rectal prolapse - version MedDRA\\23.0. | Coder Import (b) (4) | 17 Nov 2020 01:15:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 17 Nov 2020 01:15:49 |
| Data point term sent to Coder | System | 14 Nov 2020 00:02:30 |
| User entered 'rectal prolapse repair complication' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'PV Query: Please confirm the ED date(s). Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, also it was reported subject was seen back at the ED on 04 Nov 2020.' (Site from Safety). | (b) (4), (b) (6) | 14 Jan 2021 22:10:10 |
| Query 'PV Query: Please confirm the ED date(s). Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, also it was reported subject was seen back at the ED on 04 Nov 2020.' answered with 'date correct per patient' (Site from Safety). | (b) (4), (b) (6) | 13 Jan 2021 18:01:47 |
| User opened query 'PV Query: Please confirm the ED date(s). Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, also it was reported subject was seen back at the ED on 04 Nov 2020.' (Site from Safety). | (b) (4), (b) (6) | 12 Jan 2021 14:50:47 |
| User closed query 'PV Query: The onset date for the event of rectal prolapse repair complication due to constipation was updated to 10 Oct 2020 (which is prior to the surgical prolapse repair). Please reassess the onset date.' (Site from Safety). | (b) (4), (b) (6) | 04 Jan 2021 15:31:06 |
| User closed query 'PV Query: Please assess the onset date for the event of rectal prolapse repair complication due to constipation, as it was reported on 26 Oct 2020, constipation was diagnosed per PA.' (Site from Safety). | (b) (4), (b) (6) | 04 Jan 2021 15:31:04 |
| Query 'PV Query: The onset date for the event of rectal prolapse repair complication due to constipation was updated to 10 Oct 2020 (which is prior to the surgical prolapse repair). Please reassess the onset date.' answered with 'updated' (Site from Safety). | (b) (4), (b) (6) | 04 Jan 2021 00:09:07 |
| Query 'PV Query: Please assess the onset date for the event of rectal prolapse repair complication due to constipation, as it was reported on 26 Oct 2020, constipation was diagnosed per PA.' answered with 'updated' (Site from Safety). | (b) (4), (b) (6) | 04 Jan 2021 00:09:01 |
| User entered '04 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Jan 2021 00:08:55 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User opened query 'PV Query: The onset date for the event of rectal prolapse repair complication due to constipation was updated to 10 Oct 2020 (which is prior to the surgical prolapse repair). Please reassess the onset date.' (Site from Safety). | (b) (4), (b) (6) | 30 Dec 2020 21:02:46 |
| User opened query 'PV Query: Please assess the onset date for the event of rectal prolapse repair complication due to constipation, as it was reported on 26 Oct 2020, constipation was diagnosed per PA.' (Site from Safety). | | 30 Dec 2020 21:02:03 |
| User closed query 'PV Query: Please confirm the start date of rectal prolapse repair complication due to constipation, since bowel regimen were started for bowel regimen on 03-NOV-2020. | | 28 Dec 2020 15:11:11 |
| ' (Site from Safety). | | |
| Query 'PV Query: Please confirm the start date of rectal prolapse repair complication due to constipation, since bowel regimen were started for bowel regimen on 03-NOV-2020. | Whitney West (b) (4) | 23 Dec 2020 23:59:52 |
| ' answered with 'PA diagnosed constipation on 26OCT2020. Was taking colace three times daily as instructed upon discharge from her prolapse repair. She was given updated bowel regimen and presented back to the ED on 04NOV2020 for symptoms of constipation.' (Site from Safety). | (b) (4) | |
| User entered '10 Oct 2020' reason for change: Data Entry Error | Whitney West (b) (4) | 23 Dec 2020 23:59:46 |
| User opened query 'PV Query: Please confirm the start date of rectal prolapse repair complication due to constipation, since bowel regimen were started for bowel regimen on 03-NOV-2020. | (b) (4), (b) (6) | 21 Dec 2020 17:03:01 |
| ' (Site from Safety). | | |
| Query 'Please confirm the start date of rectal prolapse repair complication due to constipation, since bowel regimen were started for bowel regimen on 03-NOV-2020.' canceled (Site from Safety). | (b) (4), (b) (6) | 21 Dec 2020 17:02:09 |
| User opened query 'Please confirm the start date of rectal prolapse repair complication due to constipation, since bowel regimen were started for bowel regimen on 03-NOV-2020.' (Site from Safety). | (b) (4), (b) (6) | 21 Dec 2020 16:59:58 |
| User entered '5 Nov 2020' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '7 Nov 2020' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

Severity

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'PV Query: Since the subject was hospitalized for the events, appropriate event severity grade should be grade 4. Please update the event severity as such. If the severity is to remain grade 3, please clarify/explain.' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 15:37:07 |
| Query 'PV Query: Since the subject was hospitalized for the events, appropriate event severity grade should be grade 4. Please update the event severity as such. If the severity is to remain grade 3, please clarify/explain.' answered with 'per investigator grade was a 3' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 01:14:14 |
| User opened query 'PV Query: Since the subject was hospitalized for the events, appropriate event severity grade should be grade 4. Please update the event severity as such. If the severity is to remain grade 3, please clarify/explain.' (Site from Safety). | (b) (4), (b) (6) | 23 Nov 2020 15:33:46 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'PV Query: Please confirm the hospitalization dates. Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, however it was reported the subject was re-hospitalized from 05 Nov 2020 to 07 Nov 2020.' (Site from Safety). | (b) (4), (b) (6) | 14 Jan 2021 22:10:18 |
| Query 'PV Query: Please confirm the hospitalization dates. Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, however it was reported the subject was re-hospitalized from 05 Nov 2020 to 07 Nov 2020.' answered with 'date correct per patient' (Site from Safety). | (b) (4), (b) (6) | 13 Jan 2021 18:02:18 |
| User opened query 'PV Query: Please confirm the hospitalization dates. Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, however it was reported the subject was re-hospitalized from 05 Nov 2020 to 07 Nov 2020.' (Site from Safety). | | 12 Jan 2021 14:51:10 |
| User closed query 'PV Query: Please confirm the hospitalization dates. Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, however it was reported the subject was re-hospitalized from 05 Nov 2020 to 07 Nov 2020' (Site from Safety). | | 04 Jan 2021 15:30:35 |
| Query 'PV Query: Please confirm the hospitalization dates. Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, however it was reported the subject was re-hospitalized from 05 Nov 2020 to 07 Nov 2020' answered with 'updated' (Site from Safety). | | 04 Jan 2021 00:09:21 |
| User opened query 'PV Query: Please confirm the hospitalization dates. Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, however it was reported the subject was re-hospitalized from 05 Nov 2020 to 07 Nov 2020' (Site from Safety). | (b) (4), (b) (6) | 30 Dec 2020 21:01:00 |
| User entered '5 Nov 2020' | | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '7 Nov 2020' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

None

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #24 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 18 Feb 2021 12:46:48 |
| Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #24 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' answered with 'other action taken updated' (Site from DM). | | 17 Feb 2021 22:15:04 |
| User entered '0' reason for change: Data Entry Error | | 17 Feb 2021 22:14:48 |
| User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #24 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM). | | 24 Jan 2021 23:03:14 |
| User closed query 'Per DM CLR - RQ: Site's response noted. However, please confirm what has been updated as there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.' (Site from DM). | (b) (4), (b) (6) | 24 Dec 2020 11:24:04 |
| Query 'Per DM CLR - RQ: Site's response noted. However, please confirm what has been updated as there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 16:37:13 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

None

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User opened query 'Per DM CLR - RQ: Site's response noted. However, please confirm what has been updated as there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConPro performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise provide comment for no treatment given. ' (Sit from DM). | (b) (4), (b) (6) | 08 Dec 2020 05:32:03 |
| User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise provide comment for no treatment given. ' (Site from DM). | | 02 Dec 2020 13:50:55 |
| Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'updated' (Site from DM). | | 25 Nov 2020 01:17:44 |
| User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 09:53:13 |
| User entered '1' | | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 17 Feb 2021 22:14:48 |
| Query 'PV Query: Please clarify if the medications, magnesium citrate and sodium phosphate, were given in office or if subject had another emergency room visit for constipation.' canceled (Site from Safety). | | 29 Jan 2021 21:37:01 |
| User opened query 'PV Query: Please clarify if the medications, magnesium citrate and sodium phosphate, were given in office or if subject had another emergency room visit for constipation.' (Site from Safety). | | 29 Jan 2021 19:39:58 |
| User entered '0' | | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: Response noted, if CM is already recorded, please provide log line number ensuring indication matches with this condition. Thank you' (Site from DM). | (b) (4), (b) (6) | 26 Feb 2021 13:26:07 |
| Query 'Per CDM: Response noted, if CM is already recorded, please provide log line number ensuring indication matches with this condition. Thank you' answered with 'I'm not sure which meds you were asking about. I see bowel meds at lines: 16, 17, 24, 26, 27. | Whitney West (b) (4) | 25 Feb 2021 15:30:54 |
| Respectfully- if the work is already done then re-querying and needing to do it twice over is frustrating. Why are you unable to see the med list? ' (Site from DM). | (b) (4), (b) (6) | 22 Feb 2021 12:58:50 |
| User opened query 'Per CDM: Response noted, if CM is already recorded, please provide log line number ensuring indication matches with this condition. Thank you' (Site from DM). | (b) (4), (b) (6) | 22 Feb 2021 12:58:50 |
| User closed query 'Per DM CLR: SAE Narrative = METACLOPRAMIDE EVERY 6 HOURS. However, this is recorded as "AS NEEDED" in the Conmed eCRF. Please review and reconcile data as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 22 Feb 2021 12:46:36 |
| User closed query 'Per DM CLR: SAE Narrative = READMITTED 05NOV2020 WAS GIVEN MILK OF MAGNESIUM TWICE DAILY. However, this medication is recorded as ONCE DAILY in the CM eCRF. Please review and reconcile data as appropriate. ' (Site from DM). | (b) (4), (b) (6) | |
| Query 'Per DM CLR: SAE Narrative = METACLOPRAMIDE EVERY 6 HOURS. However, this is recorded as "AS NEEDED" in the Conmed eCRF. Please review and reconcile data as appropriate. ' answered with 'Added 'prn' (Site from DM). | Whitney West (b) (4) | 19 Feb 2021 16:23:48 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User entered 'PATIENT DISCLOSED AT DAY 85 PHONE CALL ON 13NOV2020 SHE HAD A RECTAL PROLAPSE THAT STARTED OCT08SEP2020 WHEN SHE RECEIVED A ROUTINE COLONOSCOPY AND THEN HAD A RECTAL PROLAPSE REPAIR ON 19OCT2020 AND WAS INPATIENT FROM 19OCT2020 TO 24OCT2020 THEN HAD COMPLICATIONS AND WAS INPATIENT AGAIN FROM 05NOV2020 TO 07NOV2020. PARTICIPANT RELEASED HOME AND HAS HAD SIGNIFICANT CONSTIPATION UNRELIEVED BY ENEMA X2 AND MAG CITRATE X2. READMITTED 05NOV2020 WAS GIVEN MILK OF MAGNESIUM TWICE DAILY AND METACLOPRAMIDE EVERY 6 HOURS PRN. RESOLUTION OF SYMPTOMS WITH MULTIPLE BOWEL MOVEMENTS. SENT HOME WITH PRESCRIPTION FOR MILK OF MAGNESIUM AND POLYETHYLENE GLYCOL.' | Whitney West (b) (4) | 19 Feb 2021 16:23:39 |
| reason for change: Per Query Resolution Query 'Per DM CLR: SAE Narrative = READMITTED 05NOV2020 WAS GIVEN MILK OF MAGNESIUM TWICE DAILY. However, this medication is recorded as ONCE DAILY in the CM eCRF. Please review and reconcile data as appropriate. | (b) (4), (b) (6) | 19 Feb 2021 15:47:23 |
| ' answered with 'updated con. med' (Site from DM). User closed query 'Per DM CLR: Narrative indicates that the subject was treated with Enema and Magnesium Citrate. However, there is no recorded ConMed that match the information. Please update to record the corresponding medications as appropriate. Otherwise, clarify.' (Site from DM). | | 26 Jan 2021 14:05:22 |
| User opened query 'Per DM CLR: SAE Narrative = METACLOPRAMIDE EVERY 6 HOURS. However, this is recorded as "AS NEEDED" in the Conmed eCRF. Please review and reconcile data as appropriate. ' (Site from DM). | | 24 Jan 2021 23:03:47 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User opened query 'Per DM CLR: SAE Narrative = READMITTED 05NOV2020 WAS GIVEN MILK OF MAGNESIUM TWICE DAILY. However, this medication is recorded as ONCE DAILY in the CM eCRF. Please review and reconcile data as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 24 Jan 2021 23:03:39 |
| Query 'Per DM CLR: Narrative indicates that the subject was treated with Enema and Magnesium Citrate. However, there is no recorded ConMed that match the information. Please update to record the corresponding medications as appropriate. Otherwise, clarify.' answered with 'Updated.' (Site from DM). | Whitney West (b) (4) | 20 Jan 2021 22:32:32 |
| User opened query 'Per DM CLR: Narrative indicates that the subject was treated with Enema and Magnesium Citrate. However, there is no recorded ConMed that match the information. Please update to record the corresponding medications as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 21:01:03 |
| User closed query 'PV Query: Please confirm the ED date(s). Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, also it was reported subject was seen back at the ED on 04 Nov 2020.' (Site from Safety). | (b) (4), (b) (6) | 04 Jan 2021 15:30:46 |
| Query 'PV Query: Please confirm the ED date(s). Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, also it was reported subject was seen back at the ED on 04 Nov 2020.' answered with 'updated' (Site from Safety). | | 04 Jan 2021 00:10:09 |
| User opened query 'PV Query: Please confirm the ED date(s). Per the ED records the date the subject was seen for the constipation was 07 Dec 2020, also it was reported subject was seen back at the ED on 04 Nov 2020.' (Site from Safety). | | 30 Dec 2020 21:01:20 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User closed query 'PV Query: Per follow up query response answer text labs completed are CBC, CMP, UA, Procalcitonin, CBC, lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Prottime-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID by PCR. Please provide the diagnostic test results for the above test completed and include units and reference ranges if applicable with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety). | (b) (4), (b) (6) | 29 Dec 2020 14:32:33 |
| Query 'PV Query: Per follow up query response answer text labs completed are CBC, CMP, UA, Procalcitonin, CBC, lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Prottime-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID by PCR. Please provide the diagnostic test results for the above test completed and include units and reference ranges if applicable with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' answered with 'Lab results have been emailed to email address provided. Email subject titled "Lab results for US3272169".' (Site from Safety). | | 28 Dec 2020 18:42:25 |
| User closed query 'PV Query: Please provide history of delivery, chronic constipation, and any factors to strain to pass bowel motions and weaken pelvic floor muscles.' (Site from Safety). | (b) (4), (b) (6) | 28 Dec 2020 15:10:59 |
| User closed query 'PV Query: Please confirm the severity of rectal prolapse repair complication due to constipation and hyponatremia, since these events lead to hospitalization. ' (Site from Safety). | | 28 Dec 2020 15:10:49 |

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User opened query 'PV Query: Per follow up query response answer text labs completed are CBC, CMP, UA, Procalcitonin, CBC, lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Protine-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID by PCR. Please provide the diagnostic test results for the above test completed and include units and reference ranges if applicable with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety). | (b) (4), (b) (6) | 25 Dec 2020 14:50:39 |
| Query 'PV Query: Please provide history of delivery, chronic constipation, and any factors to strain to pass bowel motions and weaken pelvic floor muscles.' answered with 'Participant denies all other routine bowel stressors or history. ' (Site from Safety). | Whitney West (b) (4) | 24 Dec 2020 00:06:07 |
| Query 'PV Query: Please confirm the severity of rectal prolapse repair complication due to constipation and hyponatremia, since these events lead to hospitalization. ' answered with 'Mild hyponatremia noted 07NOV2020 with sodium of 134. No treatment with planned recheck planned for one week later. Mild severity. | Whitney West (b) (4) | 23 Dec 2020 23:46:31 |
| Rectal prolapse repair complication due to constipation required no surgical intervention. Participant was treated with milk of magnesium and the addition of metoclopramide q6 and advanced to a regular diet over two days. Constipation was relieved and participant was released home. ' (Site from Safety). | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User entered 'PATIENT DISCLOSED AT DAY 85 PHONE CALL ON 13NOV2020 SHE HAD A RECTAL PROLAPSE THAT STARTED OCT08SEP2020 WHEN SHE RECEIVED A ROUTINE COLONOSCOPY AND THEN HAD A RECTAL PROLAPSE REPAIR ON 19OCT2020 AND WAS INPATIENT FROM 19OCT2020 TO 24OCT2020 THEN HAD COMPLICATIONS AND WAS INPATIENT AGAIN FROM 05NOV2020 TO 07NOV2020. Participant released home and has had significant constipation unrelieved by enema x2 and mag citrate x2. Readmitted 05NOV2020 was given milk of magnesium twice daily and metaclopramide every 6 hours. Resolution of symptoms with multiple bowel movements. Sent home with prescription for milk of magnesium and polyethylene glycol.' reason for change: Data Entry Error | Whitney West (b) (4) | 23 Dec 2020 23:29:09 |
| User closed query 'PV Query: Per follow up query response answer text labs completed are CBC, CMP, UA, Procalcitonin, CBC, lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Protine-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID by PCR. Please provide the diagnostic test results for the above test completed and include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 23 Dec 2020 14:31:32 |
| Query 'PV Query: Per follow up query response answer text labs completed are CBC, CMP, UA, Procalcitonin, CBC, lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Protine-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID by PCR. Please provide the diagnostic test results for the above test completed and include units and reference ranges if applicable.' answered with 'Is there an email address to send this too? Written out the results make the query response crash because the text is too long.' (Site from Safety). | Whitney West (b) (4) | 22 Dec 2020 18:14:10 |
| User opened query 'PV Query: Please provide history of delivery, chronic constipation, and any factors to strain to pass bowel motions and weaken pelvic floor muscles.' (Site from Safety). | (b) (4), (b) (6) | 21 Dec 2020 17:01:22 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User opened query 'PV Query: Please confirm the severity of rectal prolapse repair complication due to constipation and hyponatremia, since these events lead to hospitalization. ' (Site from Safety). | (b) (4), (b) (6) | 21 Dec 2020 17:00:58 |
| User opened query 'PV Query: Per follow up query response answer text labs completed are CBC, CMP, UA, Procalcitonin, CBC, lipase, Beta HCG Quantitative, POCT Creatinine, Fecal Occult Bld, Protine-INR, Amylase, C-reactive protein, Magnesium, BMP, COVID by PCR. Please provide the diagnostic test results for the above test completed and include units and reference ranges if applicable.' (Site from Safety). | | 21 Dec 2020 16:58:52 |
| Query 'PV Query: Please confirm the stop date of rectal prolapse. Stop date was reported as 08 Sep 2020, however the subject was hospitalized for the rectal prolapse repair from 19 Oct 2020-24 Oct 2020. ' canceled (Site from Safety). | | 16 Dec 2020 12:18:21 |
| User opened query 'PV Query: Please confirm the stop date of rectal prolapse. Stop date was reported as 08 Sep 2020, however the subject was hospitalized for the rectal prolapse repair from 19 Oct 2020-24 Oct 2020. ' (Site from Safety). | | 16 Dec 2020 12:17:25 |
| User entered 'patient disclosed at day 85 phone call on 13nov2020 she had a rectal prolapse that started oct08sep2020 when she received a routine colonoscopy and then had a rectal prolapse repair on 19oct2020 and was inpatient from 19oct2020 to 24oct2020 then had complications and was inpatient again from 05nov2020 to 07nov2020' | | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 14 Nov 2020 00:02:25 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per MM, please split and record each condition separately.' (Site from DM). | (b) (4), (b) (6) | 18 Dec 2020 21:01:31 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0. | Coder Import (b) (4) | 14 Dec 2020 19:07:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 14 Dec 2020 19:07:42 |
| Data point term sent to Coder | System | 14 Dec 2020 19:06:32 |
| Query 'Per MM, please split and record each condition separately.' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) | 14 Dec 2020 19:06:22 |
| Coding entries removed. | Kayla Flege (b) (4) | 14 Dec 2020 19:06:14 |
| User entered 'NAUSEA' reason for change: Data Entry Error | Kayla Flege (b) (4) | 14 Dec 2020 19:06:14 |
| User opened query 'Per MM, please split and record each condition separately.' (Site from DM). | (b) (4), (b) (6) | 12 Dec 2020 00:11:26 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\23.0. | Coder Import (b) (4) | 10 Dec 2020 20:33:04 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 10 Dec 2020 20:33:04 |
| Data point term sent to Coder | System | 01 Dec 2020 00:24:23 |
| User closed query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms. ' (Site from System). | System | 01 Dec 2020 00:23:30 |
| Query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms. ' answered with 'subject states nausea due to vomiting so they should be listed together' (Site from System). | (b) (4), (b) (6) | 01 Dec 2020 00:23:30 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User opened query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms. ' (Site from System). | Coder Import (b) (4) | 27 Nov 2020 00:28:19 |
| Data point term sent to Coder | System | 25 Nov 2020 17:15:51 |
| User entered 'Nausea/Vomitting' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '4 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User entered empty. | System | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 14:49:16 |
| User entered 'Yes (Y)' | | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '25 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 14:49:16 |
| User entered empty. | | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User entered empty. | System | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 14:49:16 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User entered '0' | System | 25 Nov 2020 17:15:11 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| User entered 'I' | System | 25 Nov 2020 17:15:11 |

US3272169

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:11 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 17:17:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 17:17:18 |
| Data point term sent to Coder | System | 25 Nov 2020 17:16:51 |
| User entered 'Constipation' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 25 Nov 2020 17:16:26 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Pelvic prolapse conditions, PT: Rectocele, LLT: Rectocele - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 17:18:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 17:18:19 |
| Data point term sent to Coder | System | 25 Nov 2020 17:17:53 |
| User entered 'rectocele' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '4 Sep 2020' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User entered empty. | System | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User entered empty. | System | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User entered '0' | System | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| User entered 'I' | System | 25 Nov 2020 17:17:36 |

US3272169

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:19 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain aggravated - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 23:19:10 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 23:19:10 |
| Data point term sent to Coder | System | 25 Nov 2020 17:18:53 |
| User entered 'worsening of abdominal pain' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '7 Sep 2020' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User entered empty. | System | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User entered empty. | System | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User entered '0' | System | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| User entered 'I' | System | 25 Nov 2020 17:18:34 |

US3272169

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:24 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per MM, please update event term to reflect etiology/ medical diagnosis if known.' (Site from DM). | (b) (4), (b) (6) | 21 Dec 2020 18:56:43 |
| Query 'Per MM, please update event term to reflect etiology/ medical diagnosis if known.' answered with 'event term correct as entered' (Site from DM). | Kayla Flege (b) (4) | 14 Dec 2020 19:08:21 |
| User opened query 'Per MM, please update event term to reflect etiology/ medical diagnosis if known.' (Site from DM). | (b) (4), (b) (6) | 12 Dec 2020 00:12:58 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Intestinal haemorrhages, PT: Rectal haemorrhage, LLT: Rectal bleeding - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 17:22:21 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 17:22:21 |
| Data point term sent to Coder | System | 25 Nov 2020 17:20:56 |
| User entered 'rectal bleeding' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '2 Sep 2020' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User entered empty. | System | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User entered empty. | System | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

Action taken with investigational product

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: Action Taken with IP = NOT APPLICABLE however, NOT APPLICABLE should only be selected if AE started BEFORE first dose, If AE started and ended during a time period when study dose was interrupted (not given/held) or, If AE started AFTER last dose? Please review and update accordingly as per CCG's.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 11:38:09 |
| Query 'Per CDM: Action Taken with IP = NOT APPLICABLE however, NOT APPLICABLE should only be selected if AE started BEFORE first dose, If AE started and ended during a time period when study dose was interrupted (not given/held) or, If AE started AFTER last dose? Please review and update accordingly as per CCG's.' answered with 'corrected' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 22:36:37 |
| User entered 'None (NONE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Jan 2021 22:36:25 |
| User opened query 'Per CDM: Action Taken with IP = NOT APPLICABLE however, NOT APPLICABLE should only be selected if AE started BEFORE first dose, If AE started and ended during a time period when study dose was interrupted (not given/held) or, If AE started AFTER last dose? Please review and update accordingly as per CCG's.' (Site from DM). | | 06 Jan 2021 13:21:32 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User entered '0' | System | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| User entered 'I' | System | 25 Nov 2020 17:20:10 |

US3272169

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:36:35 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Nov 2020 15:26:14 |
| User entered 'USA-US070-2020-mRNA-1273-P301000018' | | 30 Nov 2020 15:26:08 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 17:34:10 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 17:34:10 |
| Data point term sent to Coder | System | 25 Nov 2020 17:33:11 |
| User entered 'hyponatremia' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '5 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '7 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 25 Nov 2020 17:33:07 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 25 Nov 2020 17:32:52 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | | 25 Nov 2020 17:33:07 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System). | | 25 Nov 2020 17:33:07 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Nov 2020 17:33:07 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | System | 25 Nov 2020 17:32:52 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '5 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '7 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

None

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Is this adverse event serious? = Yes. However, there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment as applicable. Otherwise, clarify reason why no treatment is needed.' (Site from DM). | (b) (4), (b) (6) | 26 Jan 2021 14:06:55 |
| Query 'Per DM CLR: Is this adverse event serious? = Yes. However, there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment as applicable. Otherwise, clarify reason why no treatment is needed.' answered with 'Sodium was 134 and was unacknowledged until the discharge summary and was recommended that she have a follow-up BMP the following week. ' (Site from DM). | Whitney West (b) (4) | 22 Jan 2021 17:13:26 |
| User opened query 'Per DM CLR: Is this adverse event serious? = Yes. However, there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment as applicable. Otherwise, clarify reason why no treatment is needed.' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 20:49:25 |
| User entered 'I' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'SUBJECT INADVERTENTLY FORGOT TO MENTION THAT PART OF THE REASON FOR HER HOSPITALIZATION FOR THE RECTAL PROLAPSE REPAIR COMPLICATION WAS DUE TO HYPONATREMIA. RECEIVED MEDICAL RECORDS AND REPORTING THAT THIS WAS ALSO THE REASONING FOR THE INPATIENT HOSPITAL STAY FROM 05NOV2020 TO 07NOV2020. 27NOV2021 note read- mild, sodium 134, recheck BMP next week with PCP. No other treatment given.' reason for change: Data Entry Error | Whitney West (b) (4) | 22 Jan 2021 17:12:39 |
| User entered 'SUBJECT INADVERTENTLY FORGOT TO MENTION THAT PART OF THE REASON FOR HER HOSPITALIZATION FOR THE RECTAL PROLAPSE REPAIR COMPLICATION WAS Due TO HYPONATREMIA. RECEIVED MEDICAL RECORDS AND REPORTING THAT THIS WAS ALSO THE REASONING FOR THE INPATIENT HOSPITAL STAY FROM 05NOV2020 TO 07NOV2020.' reason for change: Data Entry Error | Whitney West (b) (4) | 21 Jan 2021 13:47:34 |
| User entered 'Subject inadvertently forgot to mention that part of the reason for her hospitalization for the rectal prolapse repair complication was do to hyponatremia. Received medical records and reporting that this was also the reasoning for the inpatient hospital stay from 05nov2020 to 07nov2020.' | (b) (4), (b) (6) | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 25 Nov 2020 17:32:52 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 17:15:03 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 17:15:03 |
| Data point term sent to Coder | System | 22 Jan 2021 17:14:04 |
| Coding entries removed. | Whitney West (b) (4) | 22 Jan 2021 17:14:03 |
| User entered 'VOMITING' reason for change: Data Entry Error | Whitney West (b) (4) | 22 Jan 2021 17:14:03 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0. | Coder Import (b) (4) | 14 Dec 2020 19:09:02 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 14 Dec 2020 19:09:02 |
| Data point term sent to Coder | System | 14 Dec 2020 19:07:33 |
| User entered 'Vomitting' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '4 Nov 2020' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User entered empty. | System | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 14:51:46 |
| User entered 'Yes (Y)' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '25 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 14:51:46 |
| User entered empty. | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |
| | (b) (4) | |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User entered empty. | System | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Related (NOT RELATED)' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

None

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: Please verify if this pertains to 18 REGLAN (4-NOV-2020 in the Con Med eCRF? If yes, Please review and update Other Action Taken as appropriate.' (Site from DM). | (b) (4), (b) (6) | 26 Jan 2021 14:07:20 |
| Query 'Per CDM: Please verify if this pertains to 18 REGLAN (4-NOV-2020 in the Con Med eCRF? If yes, Please review and update Other Action Taken as appropriate.' answered with 'Updated' (Site from DM). | Whitney West (b) (4) | 22 Jan 2021 17:14:09 |
| User entered '0' reason for change: Data Entry Error | Whitney West (b) (4) | 22 Jan 2021 17:14:03 |
| User opened query 'Per CDM: Please verify if this pertains to 18 REGLAN (4-NOV-2020 in the Con Med eCRF? If yes, Please review and update Other Action Taken as appropriate.' (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 12:14:16 |
| User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 12:14:16 |
| Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'info correct' (Site from DM). | (b) (4), (b) (6) | 18 Jan 2021 14:51:02 |
| User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 21:02:16 |
| User entered '1' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '1' reason for change: Per Query Resolution | Whitney West (b) (4) | 22 Jan 2021 17:14:03 |
| User entered '0' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 14:51:46 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Kayla Flege (b) (4) | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User entered '0' | System | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| User entered 'I' | System | 14 Dec 2020 19:07:18 |

US3272169

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:18 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| | | |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Dec 2020 18:25:22 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Dec 2020 18:25:22 |
| Data point term sent to Coder | System | 28 Dec 2020 18:24:23 |
| User entered 'diarrhea' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '17 Sep 2020' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 28 Dec 2020 18:23:58 |
| User entered '08:00' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Dec 2020 18:23:58 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 28 Dec 2020 18:23:38 |
| User entered empty. | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User entered '17 Sep 2020 08:00' | System | 28 Dec 2020 18:23:58 |
| User entered empty. | System | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '30 Sep 2020' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 28 Dec 2020 18:23:58 |
| User entered '08:00' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Dec 2020 18:23:58 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 28 Dec 2020 18:23:38 |
| User entered empty. | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User entered '30 Sep 2020 08:00' | System | 28 Dec 2020 18:23:58 |
| User entered empty. | System | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 28 Dec 2020 18:24:18 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 28 Dec 2020 18:24:18 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Dec 2020 18:24:18 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 28 Dec 2020 18:23:38 |
| User entered empty. | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 28 Dec 2020 18:24:18 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 28 Dec 2020 18:24:18 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Dec 2020 18:24:18 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 28 Dec 2020 18:23:38 |
| User entered empty. | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'None (NONE)' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User entered '0' | System | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| User entered 'I' | System | 28 Dec 2020 18:23:38 |

US3272169

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:35:24 |
| | | |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:21:09

Were any prior/concomitant medications and/or vaccinations taken?

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 05:00:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User closed query 'Per CDM: Response noted- please consider to add to the Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection as per your previous response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 15 Apr 2021 13:07:45 |
| Query 'Per CDM: Response noted- please consider to Whitney West add to the Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection as per your previous response. Thank you.' answered with 'Updated. Thank you.' (Site from DM). | (b) (4) (b) (4) | 14 Apr 2021 20:01:44 |
| User opened query 'Per CDM: Response noted- please consider to add to the Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection as per your previous response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 13 Apr 2021 13:36:25 |
| Query 'Per CDM: Response noted- please consider to add to the Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection as per your previous response. Thank you.' canceled (Site from DM). | (b) (4), (b) (6) | 13 Apr 2021 13:36:13 |
| User opened query 'Per CDM: Response noted- please consider to add to the Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection as per your previous response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 13 Apr 2021 13:32:34 |
| User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM). | (b) (4), (b) (6) | 13 Apr 2021 13:32:34 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:21:09

Were any prior/concomitant medications and/or vaccinations taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'cosmetic injections were last performed in 2018- insignificant to study data' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 22:10:10 |
| User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM). | (b) (4), (b) (6) | 23 Mar 2021 09:22:09 |
| User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, 3, 4, 6, 7 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. | (b) (4), (b) (6) | 17 Feb 2021 13:49:31 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Per Diary Dose 2 Day 2, 3, 4, 6, 7 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. | (b) (4), (b) (6) | 17 Feb 2021 00:05:41 |
| ' answered with 'med taken liste in con meds' (Site from DM). | | |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:21:09

Were any prior/concomitant medications and/or vaccinations taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, 3, 4, 6, 7 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM). | (b) (4), (b) (6) | 03 Feb 2021 07:25:02 |
| User closed query 'Per CDM: Per previous query response "listed". Please provide location of corresponding record(s) such as log line number. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 11:37:13 |
| Query 'Per CDM: Per previous query response "listed". Please provide location of corresponding record(s) such as log line number. Thank you. ' answered with 'med taken listed in con meds' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 23:32:39 |
| User opened query 'Per CDM: Per previous query response "listed". Please provide location of corresponding record(s) such as log line number. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 09:22:12 |
| User closed query 'Per DM CLR: Per Diary Dose 2 Day 8, 9, 10, 11, 13 and 14 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 09:22:12 |
| Query 'Per DM CLR: Per Diary Dose 2 Day 8, 9, 10, 11, 13 and 14 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'listed' (Site from DM). | (b) (4), (b) (6) | 06 Jan 2021 19:51:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:21:09

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User opened query 'Per DM CLR: Per Diary Dose 2 Day 8, 9, 10, 11, 13 and 14 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM). | (b) (4), (b) (6) | 04 Jan 2021 12:40:46 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:48:23 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

Name of Medication

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM HYDROBROMIDE, PRODUCTSYNONYM: CELEXA [CITALOPRAM HYDROBROMIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 24 Dec 2020 20:15:28 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 24 Dec 2020 20:15:28 |
| Data point term sent to Coder | System | 24 Dec 2020 20:14:47 |
| Coding entries removed. | Kayla Flege (b) (4) | 24 Dec 2020 20:14:01 |
| Coding entries removed. | Kayla Flege (b) (4) | 24 Dec 2020 20:14:01 |
| User entered 'CELEXA' reason for change: Data Entry Error | Kayla Flege (b) (4) | 24 Dec 2020 20:14:01 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM HYDROBROMIDE, PRODUCTSYNONYM: CELEXA [CITALOPRAM HYDROBROMIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Aug 2020 06:35:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Aug 2020 06:35:17 |
| Data point term sent to Coder | System | 15 Aug 2020 20:49:22 |
| User entered 'celexas' | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| | | |
| User entered 'DEPRESSION and Anxiety' reason for change: Data Entry Error | Kayla Flege (b) (4) | 24 Dec 2020 20:14:01 |
| | (b) (4) | |
| User entered 'depression' | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |
| | | |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '20' | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 16 Aug 2020 16:48:57 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | (b) (4), (b) (6) | 15 Aug 2020 20:56:23 |
| answered with 'confirm correct' (Site from System). | | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 15 Aug 2020 20:48:58 |
| User entered 'un UNK 2018' | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 15 Aug 2020 20:48:58 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: CARIPRAZINE HYDROCHLORIDE, PRODUCTSYNONYM: VRAYLAR - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Aug 2020 20:51:18 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Aug 2020 20:51:18 |
| Data point term sent to Coder | System | 15 Aug 2020 20:50:23 |
| User entered 'vraylar' | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'depression' | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '1.5' | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 16 Aug 2020 16:49:01 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | (b) (4), (b) (6) | 15 Aug 2020 20:56:32 |
| answered with 'confirm correct' (Site from System). | | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 15 Aug 2020 20:49:48 |
| User entered 'un Jun 2020' | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 15 Aug 2020 20:49:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: SOLIFENACIN SUCCINATE, PRODUCTSYNONYM: VESICARE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Aug 2020 15:05:15 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Aug 2020 15:05:15 |
| Data point term sent to Coder | System | 15 Aug 2020 20:50:23 |
| User entered 'vesicare' | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'overactive bladder' | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '5' | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 16 Aug 2020 16:49:05 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | (b) (4), (b) (6) | 15 Aug 2020 20:56:39 |
| answered with 'confirm correct' (Site from System). | | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 15 Aug 2020 20:50:20 |
| User entered 'un UNK 2019' | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 15 Aug 2020 20:50:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN, PRODUCTSYNONYM: LYRICA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 17 Aug 2020 02:04:18 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 17 Aug 2020 02:04:18 |
| Data point term sent to Coder | System | 15 Aug 2020 20:52:26 |
| User entered 'lyrica' | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 02 Nov 2020 22:06:27 |
| Query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) (b) (4) | 25 Sep 2020 19:23:38 |
| User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 05:25:11 |
| User entered 'neuropathy in neck' | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '50' | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 16 Aug 2020 16:49:09 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 20:56:46 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 15 Aug 2020 20:52:36 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 15 Aug 2020 20:52:36 |
| User entered 'UN UNK 2014' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Aug 2020 20:52:36 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 15 Aug 2020 20:52:20 |
| User entered 'un 2014' (non-conformant). | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 15 Aug 2020 20:52:20 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

Name of Medication

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Nov 2020 09:06:21 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Nov 2020 09:06:21 |
| Data point term sent to Coder | System | 20 Nov 2020 21:25:44 |
| Coding entries removed. | (b) (4), (b) (6) | 20 Nov 2020 21:25:03 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 05:02:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 05:02:47 |
| Data point term sent to Coder | System | 26 Sep 2020 15:26:37 |
| Coding entries removed. | (b) (4), (b) (6) | 26 Sep 2020 15:26:08 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Aug 2020 06:01:06 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Aug 2020 06:01:06 |
| Data point term sent to Coder | System | 15 Aug 2020 20:54:29 |
| User entered 'metoprolol er' | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA (e.g. Atrial Fibrillation, Ventricular Tachycardia, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 24 Nov 2020 13:06:57 |
| Query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA (e.g. Atrial Fibrillation, Ventricular Tachycardia, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | 20 Nov 2020 21:25:09 |
| User entered 'ARRHYTHMIA (IRREGULAR HEART BEAT) ATRIAL FIBRILLATION' reason for change: Data Entry Error | (b) (4), (b) (6) | 20 Nov 2020 21:25:03 |
| User opened query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA (e.g. Atrial Fibrillation, Ventricular Tachycardia, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 12 Nov 2020 07:46:43 |
| User closed query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 02 Nov 2020 22:07:17 |
| Query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 26 Sep 2020 15:28:39 |
| User entered 'ARRHYTHMIA (irregular heart beat)' reason for change: Data Entry Error | (b) (4), (b) (6) | 26 Sep 2020 15:26:08 |
| User opened query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 05:25:41 |
| User entered 'arrhythmia' | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '25' | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 16 Aug 2020 16:49:13 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 20:56:54 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 15 Aug 2020 20:53:32 |
| User entered 'un UNK 2018' | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 15 Aug 2020 20:53:32 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Aug 2020 16:08:16 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Aug 2020 16:08:16 |
| Data point term sent to Coder | System | 22 Aug 2020 16:06:59 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Aug 2020 16:06:14 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Aug 2020 16:06:14 |
| Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' canceled (Site from System). | Coder Import (b) (4) | 22 Aug 2020 16:06:11 |
| User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System). | Coder Import (b) (4) | 17 Aug 2020 09:56:18 |
| Data point term sent to Coder | System | 15 Aug 2020 20:54:31 |
| User entered 'flexeril' | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 02 Nov 2020 22:07:52 |
| Query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'udpated' (Site from DM). | Kayla Flege (b) (4) (b) (4) | 25 Sep 2020 19:24:04 |
| User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 05:26:19 |
| User entered 'neuropathy in neck' | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '10' | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). | (b) (4), (b) (6) | 02 Nov 2020 22:08:27 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) (b) (4) | 25 Sep 2020 19:24:15 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 05:27:10 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 16 Aug 2020 16:49:16 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 20:57:01 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 15 Aug 2020 20:54:28 |
| User entered 'un UNK 2013' | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 15 Aug 2020 20:54:28 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Aug 2020 20:56:19 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Aug 2020 20:56:19 |
| Data point term sent to Coder | System | 15 Aug 2020 20:55:32 |
| User entered 'prilosec' | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'gastroesophageal reflux disease' | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '20' | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 16 Aug 2020 16:49:22 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 20:57:09 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 15 Aug 2020 20:55:05 |
| User entered 'un Apr 2020' | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 15 Aug 2020 20:55:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: CETRIZINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Aug 2020 20:57:20 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Aug 2020 20:57:20 |
| Data point term sent to Coder | System | 15 Aug 2020 20:56:33 |
| User entered 'cetirizine' | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'seasonal allergies' | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '10' | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 16 Aug 2020 16:49:26 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | (b) (4), (b) (6) | 15 Aug 2020 20:57:16 |
| answered with 'confirm correct' (Site from System). | | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 15 Aug 2020 20:55:42 |
| User entered 'un Apr 2020' | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 15 Aug 2020 20:55:42 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Aug 2020 20:57:20 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Aug 2020 20:57:20 |
| Data point term sent to Coder | System | 15 Aug 2020 20:56:35 |
| User entered 'vitamin e' | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'nutritional supplement' | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '180' | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 16 Aug 2020 16:49:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | | 15 Aug 2020 20:56:16 |
| answered with 'confirm correct' (Site from System). | | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 15 Aug 2020 20:56:13 |
| User entered 'un Jun 2020' | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 15 Aug 2020 20:56:13 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Sep 2020 22:58:39 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Sep 2020 22:58:39 |
| Data point term sent to Coder | System | 11 Sep 2020 22:57:27 |
| User entered 'tylenol' | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location and type of INJECTION SITE PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 16:51:03 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 11:10:24 |
| Query 'Per DM CLR: Please update the indication to reflect the location and type of INJECTION SITE PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'per protocol no ae required as this is listed in ed diary' (Site from DM). | (b) (4), (b) (6) | 28 Oct 2020 15:37:32 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location and type of INJECTION SITE PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 07:38:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

Indication

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) | 20 Oct 2020 22:41:33 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6) | 02 Oct 2020 21:45:29 |
| User entered 'injection site pain' | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '1000' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 00:30:01 |
| User entered '1' | | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 00:30:01 |
| User entered 'tablet (TABLET)' | | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '16 Aug 2020' | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' reason for change: Data Entry Error | Kayla Flege (b) (4) | 20 Oct 2020 22:41:28 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | 22 Sep 2020 00:30:01 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '19 Aug 2020' reason for change: Data Entry Error | Kayla Flege (b) (4) | 20 Oct 2020 22:41:28 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 00:30:01 |
| User entered '22 Aug 2020' | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User entered empty. | System | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User entered empty. | System | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:40 |
| User entered empty. | System | 11 Sep 2020 22:56:48 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE ACETATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 15 Oct 2020 04:49:21 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 15 Oct 2020 04:49:21 |
| Data point term sent to Coder | System | 14 Oct 2020 17:35:56 |
| User entered 'Prednisolone acetate' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'yag laser posterior capsulotomy (left eye' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'I' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'drop' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|---------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'four times daily (QID)' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'topical eye' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '9 Oct 2020' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '11 Oct 2020' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User entered '4' | System | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User entered '1' | System | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:47 |
| User entered '804 (804)' | System | 14 Oct 2020 17:35:10 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

Name of Medication

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 22:59:59 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 22:59:59 |
| Data point term sent to Coder | System | 25 Nov 2020 22:59:33 |
| User entered 'bactrim' | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review AE eCRF's AE #1 GASTROENTERITIS (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 18 Feb 2021 16:15:56 |
| Query 'Per DM CLR: Please review AE eCRF's AE #1 GASTROENTERITIS (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'updated AE' (Site from DM). | (b) (4), (b) (6) | 17 Feb 2021 22:11:34 |
| User opened query 'Per DM CLR: Please review AE eCRF's AE #1 GASTROENTERITIS (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 03:26:05 |
| User entered 'gastroenteritis' | | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '800' | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 14 Apr 2021 19:02:31 |
| Signature has been broken. | (b) (4), (b) (6) | 12 Apr 2021 19:03:38 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 19:03:38 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 14 Apr 2021 19:02:31 |
| Signature has been broken. | (b) (4), (b) (6) | 12 Apr 2021 19:03:38 |
| User entered '31 Aug 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 19:03:38 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User entered '2' | System | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User entered '1' | System | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:04:54 |
| User entered '804 (804)' | System | 25 Nov 2020 22:59:00 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 23:02:39 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 23:02:39 |
| Data point term sent to Coder | System | 25 Nov 2020 23:01:34 |
| User entered 'flagyl' | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'gastroenteritis' | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '500' | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'three times daily (TID)' | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 14 Apr 2021 19:02:31 |
| Signature has been broken. | (b) (4), (b) (6) | 12 Apr 2021 19:04:07 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 19:04:07 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 14 Apr 2021 19:02:31 |
| Signature has been broken. | (b) (4), (b) (6) | 12 Apr 2021 19:04:07 |
| User entered '31 Aug 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 19:04:07 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User entered '3' | System | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User entered '1' | System | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:18 |
| User entered '804 (804)' | System | 25 Nov 2020 23:01:05 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

Name of Medication

| Audit | User | Time (GMT) |
|--|------------------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (u) (4) | 17 Feb 2021 22:58:05 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 17 Feb 2021 22:58:05 |
| Data point term sent to Coder | System | 17 Feb 2021 22:56:45 |
| Coding entries removed. | (b) (4), (b) (6) | 17 Feb 2021 22:56:21 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Nov 2020 06:48:04 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Nov 2020 06:48:04 |
| Data point term sent to Coder | System | 25 Nov 2020 23:03:35 |
| User entered 'colace' | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 09:31:36 |
| Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. | | 03 Mar 2021 21:19:34 |
| ' answered with 'subject taking to prevent further constipation' (Site from DM). | | |
| User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM). | | 02 Mar 2021 17:13:25 |
| User entered 'Yes (Y)' | | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|--|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review Con Med if also used for AE# 9 CONSTIPATION as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM). Query 'Per DM CLR: Please review Con Med if also used for AE# 9 CONSTIPATION as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' answered with 'updated indication' (Site from DM). User entered 'constipation' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Feb 2021 16:16:47 17 Feb 2021 22:56:32 17 Feb 2021 22:56:21 |
| User opened query 'Per DM CLR: Please review Con Med if also used for AE# 9 CONSTIPATION as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM). User entered 'bowel regimen' | | 29 Jan 2021 03:26:29 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '50' | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '3 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 25 Nov 2020 23:03:21 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM HYDROXIDE, PRODUCTSYNONYM: MILK OF MAGNESIA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 17 Feb 2021 22:18:05 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 17 Feb 2021 22:18:05 |
| Data point term sent to Coder | System | 17 Feb 2021 22:17:12 |
| Coding entries removed. | (b) (4), (b) (6) | 17 Feb 2021 22:16:27 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM HYDROXIDE, PRODUCTSYNONYM: MILK OF MAGNESIA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Nov 2020 10:01:11 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Nov 2020 10:01:11 |
| Data point term sent to Coder | System | 25 Nov 2020 23:04:37 |
| User entered 'milk of magnesia' | (b) (4), (b) (6) | 25 Nov 2020 23:04:33 |

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:21:09
[Prophylaxis](#)

PRODUCTION RELEASE (v12.003
EAB) (1725) 4120 of 4658

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review Con Med if also used for AE# 9 CONSTIPATION as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM). Query 'Per DM CLR: Please review Con Med if also used for AE# 9 CONSTIPATION as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 18 Feb 2021 16:17:08 |
| User entered 'constipation' reason for change: Data Entry Error | | 17 Feb 2021 22:16:35 |
| User opened query 'Per DM CLR: Please review Con Med if also used for AE# 9 CONSTIPATION as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM). | | 17 Feb 2021 22:16:27 |
| User entered 'bowel regimen' | | 29 Jan 2021 03:26:53 |
| | | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM). | (b) (4), (b) (6) | 19 Feb 2021 14:16:22 |
| Query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'dose correct per patient' (Site from DM). | | 18 Feb 2021 20:47:18 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM). | | 29 Jan 2021 03:27:03 |
| User entered '4' | | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'tablespoons' | (b) (4), (b) (6) | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'twice daily (BID)' reason for change: Data Entry Error | (b) (4), (b) (6) | 17 Feb 2021 22:16:27 |
| User entered 'once daily (QD)' | | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '3 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 17 Feb 2021 22:16:27 |
| User entered '1' | System | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 25 Nov 2020 23:04:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|--|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 17 Feb 2021 22:58:06 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 17 Feb 2021 22:58:06 |
| Data point term sent to Coder Coding entries removed. | System (b) (4), (b) (6) | 17 Feb 2021 22:57:46 17 Feb 2021 22:57:10 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 23:07:41 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 23:07:41 |
| Data point term sent to Coder User entered 'miralax' | System (b) (4), (b) (6) | 25 Nov 2020 23:05:38 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 04 Mar 2021 08:34:37 |
| Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. | | 03 Mar 2021 21:19:58 |
| ' answered with 'subject taking to prevent further constipation' (Site from DM). | | |
| User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM). | | 02 Mar 2021 17:15:10 |
| User entered 'Yes (Y)' | | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|--|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review Con Med if also used for AE# 9 CONSTIPATION as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM). Query 'Per DM CLR: Please review Con Med if also used for AE# 9 CONSTIPATION as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' answered with 'updated indication' (Site from DM). User entered 'constipation' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Feb 2021 16:17:19 17 Feb 2021 22:57:24 17 Feb 2021 22:57:10 |
| User opened query 'Per DM CLR: Please review Con Med if also used for AE# 9 CONSTIPATION as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM). User entered 'bowel regimen' | | 29 Jan 2021 03:27:26 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '17' | (b) (4), (b) (6) | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'grams' | (b) (4), (b) (6) | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '3 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 25 Nov 2020 23:05:27 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Feb 2021 00:49:01 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Feb 2021 00:49:01 |
| Data point term sent to Coder | System | 17 Feb 2021 22:58:47 |
| Coding entries removed. | (b) (4), (b) (6) | 17 Feb 2021 22:58:16 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Nov 2020 07:01:21 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Nov 2020 07:01:21 |
| Data point term sent to Coder | System | 25 Nov 2020 23:06:39 |
| User entered 'doculsate' | (b) (4), (b) (6) | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 04 Mar 2021 08:34:43 |
| Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'subject taking to prevent further constipation' (Site from DM). | | 03 Mar 2021 21:20:11 |
| User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM). | | 02 Mar 2021 17:14:19 |
| User entered 'Yes (Y)' | | 25 Nov 2020 23:06:31 |

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:21:09
Indication

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review Con Med if also used for AE# 9 CONSTIPATION as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM). Query 'Per DM CLR: Please review Con Med if also used for AE# 9 CONSTIPATION as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' answered with 'updated indication' (Site from DM). | (b) (4), (b) (6) | 18 Feb 2021 16:17:30 |
| User entered 'constipation' reason for change: Data Entry Error | | 17 Feb 2021 22:58:29 |
| User opened query 'Per DM CLR: Please review Con Med if also used for AE# 9 CONSTIPATION as the Prophylaxis field is ticked as YES. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM). | | 17 Feb 2021 22:58:16 |
| User entered 'bowel regimen' | | 29 Jan 2021 03:27:42 |
| | | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). | (b) (4), (b) (6) | 04 Mar 2021 08:34:56 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'subject stated tis dose is correct' (Site from DM). | | 03 Mar 2021 21:20:26 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). | | 02 Mar 2021 17:14:27 |
| User entered '500' | | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '3 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 25 Nov 2020 23:06:31 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE, PRODUCTSYNONYM: REGLAN [METOCLOPRAMIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Nov 2020 00:02:05 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Nov 2020 00:02:05 |
| Data point term sent to Coder | System | 25 Nov 2020 23:07:40 |
| User entered 'reglan' | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review AE eCRF's AE #14 VOMITTING (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 18 Feb 2021 16:18:22 |
| Query 'Per DM CLR: Please review AE eCRF's AE #14 VOMITTING (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'concomitant medication is marked in AE eCRF.' (Site from DM). | | 17 Feb 2021 23:00:13 |
| User opened query 'Per DM CLR: Please review AE eCRF's AE #14 VOMITTING (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM). | | 29 Jan 2021 03:28:13 |
| User entered 'nausea/vomitting' | | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '10' | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '4 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | (b) (4), (b) (6) | 18 Feb 2021 12:47:42 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Medication is still on board on an as needed basis' (Site from DM). | | 17 Feb 2021 23:12:52 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | | 24 Jan 2021 23:01:17 |
| User entered 'Yes (Y)' | | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Nov 2020 23:07:19 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 26 Nov 2020 07:22:02 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 26 Nov 2020 07:22:02 |
| Data point term sent to Coder | System | 25 Nov 2020 23:08:41 |
| User entered 'ibuprofen' | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'rectal prolapse' | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '800' | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'as needed (PRN)' reason for change: Data Entry Error | (b) (4), (b) (6) | 17 Feb 2021 23:16:40 |
| User entered 'three times daily (TID)' | | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: Please verify if this pertains to (#6) RECTAL PROLAPSE (start date 8-SEP-2020) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.' (Site from DM). | (b) (4), (b) (6) | 17 Dec 2020 14:12:28 |
| User entered '08 Sep 2020' reason for change: Data Entry Error | Kayla Flege (b) (4) | 09 Dec 2020 17:31:26 |
| Query 'Per CDM: Please verify if this pertains to (#6) RECTAL PROLAPSE (start date 8-SEP-2020) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.' answered with 'Subject started taking the medication for this indication prior to getting the diagnosis' (Site from DM). | (b) (4), (b) (6) | 01 Dec 2020 00:21:39 |
| User opened query 'Per CDM: Please verify if this pertains to (#6) RECTAL PROLAPSE (start date 8-SEP-2020) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.' (Site from DM). | | 26 Nov 2020 21:54:07 |
| User entered '2 Sep 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | (b) (4), (b) (6) | 18 Feb 2021 16:18:43 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Medication is still on board on as needed basis' (Site from DM). | | 17 Feb 2021 23:16:27 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | | 29 Jan 2021 03:28:35 |
| User entered 'Yes (Y)' | | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Feb 2021 23:16:40 |
| User entered '3' | System | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Feb 2021 23:16:40 |
| User entered '1' | System | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered empty. | System | 17 Feb 2021 23:16:40 |
| User entered '804 (804)' | System | 25 Nov 2020 23:08:02 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 23:11:00 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 23:11:00 |
| Data point term sent to Coder | System | 25 Nov 2020 23:09:42 |
| User entered 'melatonin' | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'nutritional supplement' | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '5' | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '2 Sep 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 25 Nov 2020 23:08:52 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLU-MEDROL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Nov 2020 08:35:04 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Nov 2020 08:35:04 |
| Data point term sent to Coder | System | 25 Nov 2020 23:10:43 |
| User entered 'solu-medrol' | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure to update Prophylaxis field to YES and as well MH or AE eCRF is updated to reflect this update.' (Site from DM). | (b) (4), (b) (6) | 22 Feb 2021 08:20:17 |
| Query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure to update Prophylaxis field to YES and as well MH or AE eCRF is updated to reflect this update.' answered with 'this was used to prevent a reaction during scan which needed iv contrast for rectal prolapse repair con. procedure' (Site from DM). | | 19 Feb 2021 15:52:15 |
| User opened query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure to update Prophylaxis field to YES and as well MH or AE eCRF is updated to reflect this update.' (Site from DM). | | 29 Jan 2021 03:31:21 |
| User entered 'Yes (Y)' | | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 22 Feb 2021 08:20:26 |
| Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'this was used to prevent a reaction during scan which needed iv contrast for rectal prolapse repair con. procedure' (Site from DM). | (b) (4), (b) (6) | 19 Feb 2021 15:52:21 |
| User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 03:31:11 |
| User entered 'iv contrast' | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '40' | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '4 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '4 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User entered empty. | System | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User entered empty. | System | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:32 |
| User entered empty. | System | 25 Nov 2020 23:10:40 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 23:16:06 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 23:16:06 |
| Data point term sent to Coder | System | 25 Nov 2020 23:11:45 |
| User entered 'zofran' | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure to update Prophylaxis field to YES and as well MH or AE eCRF is updated to reflect this update.' (Site from DM). | (b) (4), (b) (6) | 22 Feb 2021 08:20:31 |
| Query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure to update Prophylaxis field to YES and as well MH or AE eCRF is updated to reflect this update.' | (b) (4), (b) (6) | 19 Feb 2021 15:51:30 |
| answered with 'this was used to prevent nausea during scan which needed iv contrast for rectal prolapse repair con. procedure' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 03:32:08 |
| User opened query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure to update Prophylaxis field to YES and as well MH or AE eCRF is updated to reflect this update.' (Site from DM). | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 22 Feb 2021 08:20:33 |
| Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'this was used to prevent nausea during scan which needed iv contrast for rectal prolapse repair con. procedure' (Site from DM). | | 19 Feb 2021 15:51:36 |
| User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). | | 29 Jan 2021 03:31:40 |
| User entered 'iv contrast' | | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '8' | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '4 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '4 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User entered empty. | System | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User entered empty. | System | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:37 |
| User entered empty. | System | 25 Nov 2020 23:11:22 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 23:44:04 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 23:44:04 |
| Data point term sent to Coder | System | 25 Nov 2020 23:12:46 |
| User entered 'tramadol' | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review AE eCRF's AE #7 RECTAL PROLAPSE REPAIR COMPLICATION DUE TO CONSTIPATION (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 22 Feb 2021 11:09:26 |
| Query 'Per DM CLR: Please review AE eCRF's AE #7 RECTAL PROLAPSE REPAIR COMPLICATION DUE TO CONSTIPATION (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'updated AE' (Site from DM). | (b) (4), (b) (6) | 19 Feb 2021 15:48:40 |
| User opened query 'Per DM CLR: Please review AE eCRF's AE #7 RECTAL PROLAPSE REPAIR COMPLICATION DUE TO CONSTIPATION (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 03:33:31 |
| User entered 'rectal prolapse repair' | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '50' | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM). | (b) (4), (b) (6) | 04 Mar 2021 08:49:01 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 03 Mar 2021 21:26:55 |
| User entered '08 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 03 Mar 2021 21:26:46 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM). | (b) (4), (b) (6) | 02 Mar 2021 17:15:26 |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | (b) (4), (b) (6) | 22 Feb 2021 11:10:10 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated end date' (Site from DM). | (b) (4), (b) (6) | 19 Feb 2021 15:49:42 |
| User entered 'No (N)' reason for change: Data Entry Error | | 19 Feb 2021 15:49:30 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | | 29 Jan 2021 03:33:41 |
| User entered 'Yes (Y)' | | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '07 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Feb 2021 15:49:30 |
| User entered empty. | | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User entered empty. | System | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User entered empty. | System | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:53 |
| User entered empty. | System | 25 Nov 2020 23:12:18 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE SODIUM;SENNOSIDE A+B, PRODUCTSYNONYM: PERI-COLACE [DOCUSATE SODIUM;SENNOSIDE A+B] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Dec 2020 15:31:19 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Dec 2020 15:31:19 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE;SENN ALEXANDRINA, PRODUCTSYNONYM: DOCUSATE;SENN A - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Nov 2020 09:57:03 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Nov 2020 09:57:03 |
| Data point term sent to Coder | System | 25 Nov 2020 23:13:49 |
| User entered 'senna-docusane (pericolace)' | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'constipation' | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '8.6/50' | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '4 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '7 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User entered '1' | System | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User entered '1' | System | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:05:57 |
| User entered '804 (804)' | System | 25 Nov 2020 23:13:29 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 23:16:06 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Nov 2020 23:16:06 |
| Data point term sent to Coder | System | 25 Nov 2020 23:14:49 |
| User entered 'albuterol' | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mild asthma' | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '2' | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'puff (PUFF)' reason for change: Data Entry Error | Kayla Flege (b) (4) | 09 Dec 2020 17:30:42 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: Please review if Puff is an available unit in the list of available options. Kindly review and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 16 Dec 2020 21:02:33 |
| Query 'Per CDM: Please review if Puff is an available unit in the list of available options. Kindly review and update as appropriate.' answered with 'updated' (Site from DM). | Kayla Flege (b) (4) | 09 Dec 2020 17:30:47 |
| User entered empty; reason for change Data Entry Error | Kayla Flege (b) (4) | 09 Dec 2020 17:30:42 |
| User opened query 'Per CDM: Please review if Puff is an available unit in the list of available options. Kindly review and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 02 Dec 2020 10:18:41 |
| User entered 'puffs' | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'UN UNK 2000' | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 25 Nov 2020 23:14:26 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Jan 2021 15:29:04 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Jan 2021 15:29:04 |
| Data point term sent to Coder | System | 20 Jan 2021 15:28:02 |
| User entered 'Magnesium citrate' | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Constipation' | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '300' | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'mL (mL)' | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'as needed (PRN)' | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Oral (ORAL)' | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '01 Nov 2020' | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Whitney West (b) (4) | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Jan 2021 15:27:14 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: SODIUM PHOSPHATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Jan 2021 17:01:07 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Jan 2021 17:01:07 |
| Data point term sent to Coder | System | 20 Jan 2021 15:30:03 |
| User entered 'Sodium Phosphate' reason for change: | Whitney West (b) (4) | 20 Jan 2021 15:29:58 |
| Data Entry Error | (b) (4) | |
| User entered 'Fleets enema' | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Jan 2021 15:29:58 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Jan 2021 15:29:58 |
| User entered 'No (N)' reason for change: Data Entry Error | Whitney West (b) (4) | 20 Jan 2021 15:29:58 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 20 Jan 2021 15:29:33 |
| User entered empty. | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Jan 2021 15:29:58 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Jan 2021 15:29:58 |
| User entered 'Constipation' reason for change: Data Entry Error | Whitney West (b) (4) | 20 Jan 2021 15:29:58 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 20 Jan 2021 15:29:33 |
| User entered empty. | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '19/7/197' | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Other (OTHER)' | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: Response noted. As per previous query, please remove the 'numeri's' (19, 7, and 197) from the 'dose unit is Other, specify' field. Thank you' (Site from DM). | (b) (4), (b) (6) | 04 Mar 2021 08:49:52 |
| Query 'Per CDM: Response noted. As per previous query, please remove the 'numeri's' (19, 7, and 197) from the 'dose unit is Other, specify' field. Thank you' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 03 Mar 2021 21:29:38 |
| User entered 'g/g/ml' reason for change: Data Entry Error | (b) (4), (b) (6) | 03 Mar 2021 21:29:24 |
| User opened query 'Per CDM: Response noted. As per previous query, please remove the 'numeri's' (19, 7, and 197) from the 'dose unit is Other, specify' field. Thank you' (Site from DM). | (b) (4), (b) (6) | 26 Feb 2021 11:44:01 |
| User closed query 'Per DM CLR: Please remove the extraneous data (ie. 19/7/197) in the Dose unit field as this is already recorded in the DOSE FIELD as appropriate.' (Site from DM). | (b) (4), (b) (6) | 26 Feb 2021 11:44:01 |
| Query 'Per DM CLR: Please remove the extraneous data (ie. 19/7/197) in the Dose unit field as this is already recorded in the DOSE FIELD as appropriate.' answered with 'Not a date. Dose. ' (Site from DM). | Whitney West (b) (4) | 25 Feb 2021 15:27:05 |
| User opened query 'Per DM CLR: Please remove the extraneous data (ie. 19/7/197) in the Dose unit field as this is already recorded in the DOSE FIELD as appropriate.' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 09:30:21 |
| User entered '19g/7g/197mL' | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'as needed (PRN)' | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Route of administration](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Rectal (RECTAL)' | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '01 Nov 2020' | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '0' | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '07 Nov 2020' | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'No (N)' | Whitney West (b) (4) | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User entered empty. | System | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User entered empty. | System | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:21:09

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:40 |
| User entered empty. | System | 20 Jan 2021 15:29:33 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:21:09

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 05:00:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yes (Y)' reason for change: New Information | (b) (4), (b) (6) | 14 Oct 2020 17:26:37 |
| User entered 'No (N)' | | 15 Aug 2020 20:48:18 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:21:09

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Nov 2020 22:06:14 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Nov 2020 22:06:14 |
| User entered '19 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 20 Nov 2020 22:06:14 |
| DataPoint activated with code reason code Data required. | (b) (4), (b) (6) | 20 Nov 2020 22:05:54 |
| DataPoint inactivated with code reason code Data not required. | Kayla Flege (b) (4) | 20 Oct 2020 22:45:56 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 20 Oct 2020 22:45:44 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Oct 2020 22:45:44 |
| User entered empty; reason for change Data Entry Error | Kayla Flege (b) (4) | 20 Oct 2020 22:45:44 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 14 Oct 2020 17:27:58 |
| User entered 'un May 2014' (non-conformant). | (b) (4), (b) (6) | 14 Oct 2020 17:27:58 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:21:09

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Nov 2020 22:06:14 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Nov 2020 22:06:14 |
| User entered 'rectal prolapse repair' reason for change: Data Entry Error | (b) (4), (b) (6) | 20 Nov 2020 22:06:14 |
| DataPoint activated with code reason code Data required. | (b) (4), (b) (6) | 20 Nov 2020 22:05:54 |
| DataPoint inactivated with code reason code Data not required. | Kayla Flege (b) (4) | 20 Oct 2020 22:45:56 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 20 Oct 2020 22:45:44 |
| User entered empty; reason for change Data Entry Error | Kayla Flege (b) (4) | 20 Oct 2020 22:45:44 |
| User entered 'Cataract surgery (left eye)' | (b) (4), (b) (6) | 14 Oct 2020 17:27:58 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Nov 2020 22:06:14 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Nov 2020 22:06:14 |
| User entered 'Adverse Event (AE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 20 Nov 2020 22:06:14 |
| DataPoint activated with code reason code Data required. | (b) (4), (b) (6) | 20 Nov 2020 22:05:54 |
| DataPoint inactivated with code reason code Data not required. | Kayla Flege (b) (4) | 20 Oct 2020 22:45:56 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 20 Oct 2020 22:45:44 |
| User entered empty; reason for change Data Entry Error | Kayla Flege (b) (4) | 20 Oct 2020 22:45:44 |
| User entered 'Medical History (MH)' | (b) (4), (b) (6) | 14 Oct 2020 17:27:58 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:21:09

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| DataPoint activated with code reason code Data required. | (b) (4), (b) (6) | 20 Nov 2020 22:05:54 |
| DataPoint inactivated with code reason code Data not required. | Kayla Flege (b) (4) | 20 Oct 2020 22:45:56 |
| User entered empty. | (b) (4), (b) (6) | 14 Oct 2020 17:27:58 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:21:09

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:39:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '8 Oct 2020' | (b) (4), (b) (6) | 14 Oct 2020 17:28:37 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:21:09

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:39:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Yag laser posterior capsulotomy (left eye)' | (b) (4), (b) (6) | 14 Oct 2020 17:28:37 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:39:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Medical History (MH)' | (b) (4), (b) (6) | 14 Oct 2020 17:28:37 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:21:09

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:39:35 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 14 Oct 2020 17:28:37 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:21:09

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:39:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '4 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:16:40 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:21:09

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:39:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'ct imaging (abdomen/pelvis)' | (b) (4), (b) (6) | 25 Nov 2020 23:16:40 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:39:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Adverse Event (AE)' | (b) (4), (b) (6) | 25 Nov 2020 23:16:40 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:21:09

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:39:46 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:16:40 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:21:09

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:39:48 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '5 Nov 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:17:15 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:21:09

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:39:48 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'ct imaging (abdomen/pelvis)' | (b) (4), (b) (6) | 25 Nov 2020 23:17:15 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:39:48 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Adverse Event (AE)' | (b) (4), (b) (6) | 25 Nov 2020 23:17:15 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:21:09

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:39:48 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:17:15 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:21:09

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:00 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '4 Sep 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:38:04 |

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:21:09

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:00 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'esophagogastroduodenoscopy (egd)' | (b) (4), (b) (6) | 25 Nov 2020 23:38:04 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:00 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Adverse Event (AE)' | (b) (4), (b) (6) | 25 Nov 2020 23:38:04 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:21:09

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:00 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:38:04 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:21:09

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '7 Sep 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:38:53 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:21:09

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'ct imaging (abdomen/pelvis)' | (b) (4), (b) (6) | 25 Nov 2020 23:38:53 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Adverse Event (AE)' | (b) (4), (b) (6) | 25 Nov 2020 23:38:53 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:21:09

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:08 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty. | (b) (4), (b) (6) | 25 Nov 2020 23:38:53 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:21:09

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:26 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '15 Oct 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:39:52 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:21:09

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:26 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'electrocardiogram' | (b) (4), (b) (6) | 25 Nov 2020 23:39:52 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:26 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 25 Nov 2020 23:39:52 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:21:09

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:26 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'pre-op physical' | (b) (4), (b) (6) | 25 Nov 2020 23:39:52 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:21:09

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '15 Oct 2020' | (b) (4), (b) (6) | 25 Nov 2020 23:40:29 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:21:09

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'chest x-ray' | (b) (4), (b) (6) | 25 Nov 2020 23:40:29 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 25 Nov 2020 23:40:29 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:21:09

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:29 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'pre-op physical' | (b) (4), (b) (6) | 25 Nov 2020 23:40:29 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:21:09

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered '8 Sep 2020' | Kayla Flege (b) (4) | 09 Dec 2020 16:37:02 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:21:09

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered 'routine COLONOSCOPY' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Mar 2021 15:49:34 |
| User entered 'screening COLONOSCOPY' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Mar 2021 15:49:11 |
| User entered 'routine colonoscopy' | Kayla Flege (b) (4) | 09 Dec 2020 16:37:02 |
| | (b) (4) | |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User closed query 'Per CDM: "Diagnostic" is an available option from the selection list for this data field. Please update to select the appropriate option and ensure to update ' If indication is Other, specify' accordingly. Thank you' (Site from DM). | (b) (4), (b) (6) | 15 Mar 2021 16:04:09 |
| Query 'Per CDM: "Diagnostic" is an available option from the selection list for this data field. Please update to select the appropriate option and ensure to update ' If indication is Other, specify' accordingly. Thank you' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 12 Mar 2021 23:56:06 |
| User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System). | System | 12 Mar 2021 23:55:59 |
| User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System). | System | 12 Mar 2021 23:55:49 |
| User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Mar 2021 23:55:49 |
| User opened query 'Per CDM: "Diagnostic" is an available option from the selection list for this data field. Please update to select the appropriate option and ensure to update ' If indication is Other, specify' accordingly. Thank you' (Site from DM). | | 11 Mar 2021 08:45:58 |
| User closed query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify. ' (Site from DM). | | 11 Mar 2021 08:45:58 |
| Query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM). | | 10 Mar 2021 15:50:07 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:21:09

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User opened query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify. ' (Site from DM). | (b) (4), (b) (6) | 04 Mar 2021 10:55:19 |
| User entered 'Other (OTHER)' | Kayla Flege (b) (4) (b) (4) | 09 Dec 2020 16:37:02 |

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:21:09

If indication is Other, specify

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:39 |
| User signature succeeded. | Adam Brosz (b) (4) | 09 Apr 2021 15:00:56 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 12 Mar 2021 23:55:59 |
| User entered 'diagnostic' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Mar 2021 15:49:50 |
| User entered 'Routine' | Kayla Flege (b) (4) | 09 Dec 2020 16:37:02 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '16/Nov/2020 10:32' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'I' | | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '24/Nov/2020 13:11' | System | 24 Nov 2020 13:11:31 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Nov 2020 14:59:11 |
| User entered 'I' | | 24 Nov 2020 13:11:31 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '25/Nov/2020 10:36' | System | 25 Nov 2020 15:36:07 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Nov 2020 14:59:11 |
| User entered 'I' | | 25 Nov 2020 15:36:07 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '30/Nov/2020 15:01' | System | 30 Nov 2020 15:01:08 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Nov 2020 15:26:30 |
| User entered 'I' | | 30 Nov 2020 15:01:08 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '30/Nov/2020 15:26' | System | 30 Nov 2020 15:26:46 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Dec 2020 16:03:09 |
| User entered 'I' | | 30 Nov 2020 15:26:46 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '10/Dec/2020 13:56' | System | 10 Dec 2020 18:56:21 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Dec 2020 16:03:09 |
| User entered 'I' | | 10 Dec 2020 18:56:21 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '16/Dec/2020 11:03' | System | 16 Dec 2020 16:03:25 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Dec 2020 15:12:39 |
| User entered 'I' | | 16 Dec 2020 16:03:25 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '28/Dec/2020 10:12' | System | 28 Dec 2020 15:12:53 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Jan 2021 15:31:21 |
| User entered 'I' | | 28 Dec 2020 15:12:53 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '04/Jan/2021 10:31' | System | 04 Jan 2021 15:31:33 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:52:02 |
| User entered 'I' | | 04 Jan 2021 15:31:33 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '22/Jan/2021 15:52' | System | 22 Jan 2021 15:52:14 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Jan 2021 02:29:13 |
| User entered 'I' | | 22 Jan 2021 15:52:14 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '24/Jan/2021 21:29' | System | 25 Jan 2021 02:29:22 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Jan 2021 13:24:30 |
| User entered 'I' | | 25 Jan 2021 02:29:22 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '19/Feb/2021 17:30' | System | 19 Feb 2021 17:30:11 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Feb 2021 17:33:41 |
| User entered 'I' | (b) (4), (b) (6) | 19 Feb 2021 17:30:11 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '26/Feb/2021 09:48' | System | 26 Feb 2021 14:48:24 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Mar 2021 15:06:10 |
| Un-reviewed for Safety. | | 26 Feb 2021 14:48:24 |
| User entered '1' reason for change: Data Entry Error | | 26 Feb 2021 14:48:24 |
| Reviewed for Safety. | | 19 Feb 2021 17:33:41 |
| User entered '0' | | 19 Feb 2021 17:30:11 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'USA-US070-2020-MRNA-1273-P301000018' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'No (N)' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Adam' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Brosz' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '2444 W. Faidley Ave' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'Grand Island' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered 'NE' | System | 16 Nov 2020 15:31:13 |

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Nov 2020 15:32:03 |
| User entered '68803' | System | 16 Nov 2020 15:31:13 |

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Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:11:23 |
| User entered 'US' | System | 16 Nov 2020 15:32:09 |

US3272169

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Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 11 Mar 2021 15:07:35 |
| User entered '13' | System | 26 Feb 2021 14:48:24 |
| User entered '12' | System | 19 Feb 2021 17:30:11 |
| User entered '11' | System | 25 Jan 2021 02:29:22 |
| User entered '10' | System | 22 Jan 2021 15:52:14 |
| User entered '9' | System | 04 Jan 2021 15:31:33 |
| User entered '8' | System | 28 Dec 2020 15:12:53 |
| User entered '7' | System | 16 Dec 2020 16:03:25 |
| User entered '6' | System | 10 Dec 2020 18:56:21 |
| User entered '5' | System | 30 Nov 2020 15:26:46 |
| User entered '4' | System | 30 Nov 2020 15:01:08 |
| User entered '3' | System | 25 Nov 2020 15:36:07 |
| User entered '2' | System | 24 Nov 2020 13:11:31 |
| User entered '1' | System | 16 Nov 2020 15:32:09 |

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Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (15)

Generated On: 09 Jun 2021 16:21:09

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered '11/Mar/2021 09:07' | System | 11 Mar 2021 15:07:35 |

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Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (15)

Generated On: 09 Jun 2021 16:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Adam Brosz (b) (4) | 29 Apr 2021 17:49:08 |
| User entered 'I' | (b) (4), (b) (6) | 11 Mar 2021 15:07:35 |