US3292241 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:21:07

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**US3292241**
**Form: Participant Creation**
**Data signed:** (b) (4) **22 Feb 2021 21:16:56**
**Generated On: 11 Aug 2021 22:21:07**

| Participant ID | US3292241 |
|---|---|

mRNA-1273-P301 Completion Guidelines



FDA-CBER-2022-1614-1683514

**US3292241**
**Folder: Screening**
**Form: Visit Date**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was this visit performed? | Yes ■<br>No ☐ |
| Visit date (dd MMM yyyy) | 20 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ■ |
| Folder OID | SCRN |



FDA-CBER-2022-1614-1683515

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Date of Birth (MMM yyyy) | (b) (6) 1953 |
| Age | 67 |
| Age Units | YEARS |
| Age (Derived) | 67 |
| Sex | Female ■<br>Male ☐ |
| Ethnicity | Hispanic or Latino ☐<br>Not Hispanic or Latino ■<br>Not Reported ☐<br>Unknown ☐ |
| 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 |

**US3292241**
**Folder: Screening**
**Form: Enrollment**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Date of Informed Consent *(dd MMM yyyy)* | 20 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 ☐<br>Amendment 2 ■<br>Amendment 3 ☐<br>Amendment 4 ☐<br>Amendment 5 ☐ |
| Was participant enrolled in the study? | Yes ■<br>No ☐ |
| If No, indicate reason for screen fail | Withdrew Consent ☐<br>Inclusion/Exclusion ☐<br>Cohort Full ☐<br>Other ☐ |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes ☐<br>No ■ |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |



FDA-CBER-2022-1614-1683517

**US3292241**
**Folder: Screening**
**Form: Inclusion/Exclusion Criteria Summary**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
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Did the participant meet all eligibility criteria?

Yes ■
No ☐

**US3292241**
**Folder: Screening**
**Form: Medical History Summary**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
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Were any significant conditions reported? Yes ■ No ☐



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**US3292241**
**Folder: Screening**
**Form: Medical History (1)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | ALLERGY TO SULFA DRUGS |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

**US3292241**
**Folder: Screening**
**Form: Medical History (2)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | SEASONAL ALLERGIES - CEDAR |
| Start date (dd MMM yyyy) | UN UNK 1959 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1959 |
| Start Year (derived) | 1959 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |



FDA-CBER-2022-1614-1683521

**US3292241**
**Folder: Screening**
**Form: Medical History (3)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | SEASONAL ALLERGIES - OAK |
| Start date (dd MMM yyyy) | UN UNK 1959 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1959 |
| Start Year (derived) | 1959 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |



FDA-CBER-2022-1614-1683522

**US3292241**
**Folder: Screening**
**Form: Medical History (4)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | SEASONAL ALLERGIES - MOLD |
| Start date (dd MMM yyyy) | UN UNK 1959 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1959 |
| Start Year (derived) | 1959 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

**US3292241**
**Folder: Screening**
**Form: Medical History (5)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | FOOD ALLERGY - MELON |
| Start date (dd MMM yyyy) | UN UNK 1960 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1960 |
| Start Year (derived) | 1960 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

**US3292241**
**Folder: Screening**
**Form: Medical History (6)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | ALLERGY - LATEX |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

**US3292241**
**Folder: Screening**
**Form: Medical History (7)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | HORMONE REPLACEMENT THERAPY |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |



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**US3292241**
**Folder: Screening**
**Form: Medical History (8)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | CHOLECYSTECTOMY |
| Start date (dd MMM yyyy) | UN UNK 2003 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ☐<br>No ■ |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2003 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2003 |
| Start Year (derived) | 2003 |
| Stop Month and Year (derived) | JAN 2003 |
| Stop Year (derived) | 2003 |

**US3292241**
**Folder: Screening**
**Form: Medical History (9)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | THYROIDECTOMY |
| Start date (dd MMM yyyy) | UN UNK 2001 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ☐<br>No ■ |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2001 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2001 |
| Start Year (derived) | 2001 |
| Stop Month and Year (derived) | JAN 2001 |
| Stop Year (derived) | 2001 |



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**US3292241**
**Folder: Screening**
**Form: Medical History (10)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | VAGINAL DELIVERY |
| Start date (dd MMM yyyy) | UN UNK 1989 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes<br>No |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 1989 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1989 |
| Start Year (derived) | 1989 |
| Stop Month and Year (derived) | JAN 1989 |
| Stop Year (derived) | 1989 |

**US3292241**
**Folder: Screening**
**Form: Medical History (11)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | VAGINAL DELIVERY |
| Start date (dd MMM yyyy) | UN UNK 1991 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes<br>No |
| 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 |

**US3292241**
**Folder: Screening**
**Form: Medical History (12)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | DISCECTOMY - C5-C6 |
| Start date (dd MMM yyyy) | UN UNK 2007 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ☐<br>No ■ |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2007 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2007 |
| Start Year (derived) | 2007 |
| Stop Month and Year (derived) | JAN 2007 |
| Stop Year (derived) | 2007 |

**US3292241**
**Folder: Screening**
**Form: Medical History (13)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | TOTAL HYSTERECTOMY |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ☐<br>No ■ |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | JAN 2000 |
| Stop Year (derived) | 2000 |

**US3292241**
**Folder: Screening**
**Form: Medical History (14)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | BILATERAL SALPINGO - OOPHORECTOMY |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ☐<br>No ■ |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | JAN 2000 |
| Stop Year (derived) | 2000 |



FDA-CBER-2022-1614-1683533

**US3292241**
**Folder: Screening**
**Form: Medical History (15)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | MYOPIA |
| Start date (dd MMM yyyy) | UN UNK 1967 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1967 |
| Start Year (derived) | 1967 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

**US3292241**
**Folder: Screening**
**Form: Medical History (16)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | DRY EYES |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

**US3292241**
**Folder: Screening**
**Form: Medical History (17)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | ASTHMA |
| Start date (dd MMM yyyy) | UN UNK 1983 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1983 |
| Start Year (derived) | 1983 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

**US3292241**
**Folder: Screening**
**Form: Medical History (18)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |



FDA-CBER-2022-1614-1683537

**US3292241**
**Folder: Screening**
**Form: Medical History (19)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | CONSTIPATION |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |



FDA-CBER-2022-1614-1683538

**US3292241**
**Folder: Screening**
**Form: Medical History (20)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | CHOLELITHIASIS |
| Start date (dd MMM yyyy) | UN UNK 2003 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ☐<br>No ■ |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2003 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2003 |
| Start Year (derived) | 2003 |
| Stop Month and Year (derived) | JAN 2003 |
| Stop Year (derived) | 2003 |

**US3292241**
**Folder: Screening**
**Form: Medical History (21)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | HYPOTHYROIDISM |
| Start date (dd MMM yyyy) | UN UNK 2001 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2001 |
| Start Year (derived) | 2001 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |



FDA-CBER-2022-1614-1683540

**US3292241**
**Folder: Screening**
**Form: Medical History (22)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | HYPERTHYROIDISM |
| Start date (dd MMM yyyy) | UN UNK 2001 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ☐<br>No ■ |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2001 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2001 |
| Start Year (derived) | 2001 |
| Stop Month and Year (derived) | JAN 2001 |
| Stop Year (derived) | 2001 |



FDA-CBER-2022-1614-1683541

**US3292241**
**Folder: Screening**
**Form: Medical History (23)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | SURGICAL MENOPAUSE |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |



FDA-CBER-2022-1614-1683542

**US3292241**
**Folder: Screening**
**Form: Medical History (24)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | BULGING DISC (C5,C6) |
| Start date (dd MMM yyyy) | UN UNK 2007 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes<br>No |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2007 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2007 |
| Start Year (derived) | 2007 |
| Stop Month and Year (derived) | JAN 2007 |
| Stop Year (derived) | 2007 |

**US3292241**
**Folder: Screening**
**Form: Medical History (25)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | INSOMNIA |
| Start date (dd MMM yyyy) | UN UNK 2015 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2015 |
| Start Year (derived) | 2015 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |



FDA-CBER-2022-1614-1683544

**US3292241**
**Folder: Screening**
**Form: Medical History (26)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | URINARY INCONTINENCE |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |



FDA-CBER-2022-1614-1683545

**US3292241**
**Folder: Screening**
**Form: Medical History (27)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Condition | UTERINE FIBROIDS |
| Start date (dd MMM yyyy) | UN UNK 1973 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ☐<br>No ■ |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1973 |
| Start Year (derived) | 1973 |
| Stop Month and Year (derived) | JAN 2000 |
| Stop Year (derived) | 2000 |

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Were vital signs assessed? | Yes ■<br>No ☐ |
| Date of assessment *(dd MMM yyyy)* | 20 AUG 2020 |
| Time of assessment *(00:00-23:59)* | 09:05 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 09:05 |
| Height *(xxx.x)* | 163.3 cm |
| Weight *(xxx.x)* | 72.4 kg |
| BMI *(xxx.x)* | 27.14977 kg/m$^2$ |
| BMI units | KG/M2 |
| Temperature *(xxx.x)* | ND - Not Done |
| Route of measurement | Oral ☐<br>Axillary ☐<br>Other ☐ |
| 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) | |



FDA-CBER-2022-1614-1683547

**US3292241**
**Folder: Screening**
**Form: Physical Examination**
**Data signed:** (b) (4) **22 Feb 2021 21:17:02**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was the physical examination performed? | Yes ■<br>No ☐ |
| Date of examination *(dd MMM yyyy)* | 20 AUG 2020 |

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



FDA-CBER-2022-1614-1683548

**US3292241**
**Folder: Screening**
**Form: Childbearing Potential**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Date of assessment *(dd MMM yyyy)* | 20 AUG 2020 |
| Is the participant of childbearing potential? | Yes ☐<br>No ■ |
| If No, what is the reason? | Surgically sterile ■<br>Post-menopausal ☐<br>Partner medically sterile ☐<br>Not reached age of Menarche ☐<br>Other ☐ |
| If Partner medically sterile or Other, specify | |
| If Surgically sterile, date of surgery *(dd MMM yyyy)* | UN UNK 2000 |
| Date of surgery unknown | False |
| If Post-menopausal, date of last menstruation *(dd MMM yyyy)* | |
| Date of last menstruation unknown | False |

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

| **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 |

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| **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** | |



FDA-CBER-2022-1614-1683551

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Visit Date**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was this visit performed? | Yes ■<br>No ☐ |
| Visit date (dd MMM yyyy) | 20 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ■ |
| Folder OID | VISIT1 |



FDA-CBER-2022-1614-1683552

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| What was the date of randomization? *(dd MMM yyyy)* | 20 AUG 2020 |
| What was the participant's randomization number? | 187240 |
| In what Cohort was the participant enrolled? | >=18 and <65 years and not at risk ☐<br>>=18 and <65 years and at risk ☐<br>>=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 ☐<br>No ■ |
| Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) | Yes ☐<br>No ■ |
| Severe obesity (body mass index > or = 40kg/m2 | Yes ☐<br>No ■ |
| Diabetes (Type I, Type 2, or gestational) | Yes ☐<br>No ■ |
| Liver Disease | Yes ☐<br>No ■ |
| Human Immunodeficiency Virus (HIV) infection | Yes ☐<br>No ☐ |



FDA-CBER-2022-1614-1683553

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

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

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose ■<br>Post-Dose ☐ |
| Were vital signs assessed? | Yes ■<br>No ☐ |
| Date of assessment *(dd MMM yyyy)* | 20 AUG 2020 |
| Time of assessment *(00:00-23:59)* | 10:40 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 10:40 |
| Temperature *(xxx.x)* | 36.8 C |
| Route of measurement | Oral ■<br>Axillary ☐<br>Other ☐ |
| If Other, specify | |
| Pulse *(xxx)* | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate *(xxx)* | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure *(xxx)* | 142 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure *(xxx)* | 93 mmHg |
| Diastolic Blood Pressure units | MMHG |



FDA-CBER-2022-1614-1683555

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose ☐<br>Post-Dose ■ |
| Were vital signs assessed? | Yes ■<br>No ☐ |
| Date of assessment *(dd MMM yyyy)* | 20 AUG 2020 |
| Time of assessment *(00:00-23:59)* | 12:45 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 12:45 |
| Temperature *(xxx.x)* | 36.5 C |
| Route of measurement | Oral ■<br>Axillary ☐<br>Other ☐ |
| If Other, specify | |
| Pulse *(xxx)* | 63 beats/min |
| Pulse units | BPM |
| Respiratory Rate *(xxx)* | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure *(xxx)* | 150 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure *(xxx)* | 93 mmHg |
| Diastolic Blood Pressure units | MMHG |

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Physical Examination**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

Was the physical examination performed? Yes ☐ No ☒

Date of examination *(dd MMM yyyy)* _____

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



FDA-CBER-2022-1614-1683557

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was study treatment given? | Yes ■<br>No ☐ |
| If No, reason not given | Participant declined due to Adverse Event ☐<br>Physician withheld dose due to Adverse Event ☐<br>Death ☐<br>Lost To Follow-Up ☐<br>Physician Decision ☐<br>Pregnancy ☐<br>Protocol Deviation ☐<br>Study Terminated by Sponsor ☐<br>Withdrawal of Consent by Participant ☐<br>Confirmed COVID-19 ☐<br>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)* | 20 AUG 2020 |
| What was the treatment time? *(00:00-23:59)* | 12:08 (24 HR) |
| Treatment Date and Time (derived) | 20 AUG 2020 12:08 |
| Which arm was used to give treatment? | Left Arm ■<br>Right Arm ☐ |
| What was the frequency of the study treatment dosing? | ONCE |
| What was the route of administration for the study treatment? | INTRAMUSCULAR |



FDA-CBER-2022-1614-1683558

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Immunogenicity Assessment**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was the sample collected? | Yes ■<br>No ☐ |
| Collection date *(dd MMM yyyy)* | 20 AUG 2020 |
| Collection time *(00:00-23:59)* | 10:52 (24 HR) |
| Collection date and time (derived) | 20 AUG 2020 10:52 |



FDA-CBER-2022-1614-1683559

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

| Collection date *(dd MMM yyyy)* | | | 20 AUG 2020 |
|---|---|---|---|
| Lab Test | Was the sample collected? | Collection time *(00:00 - 23:59)* | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:21 | 20 AUG 2020 11:21 |
| Nasopharyngeal Swab 2 | No | | |



FDA-CBER-2022-1614-1683560

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Continuing**
**Data signed:** (b) (4) **22 Feb 2021 21:17:30**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-1683561

| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 97.7 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ■ |

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

| | |
|---|---|
| PC Time Stamp | 20 AUG 2020 12:50 |
| PC Open Date & Time | 20 AUG 2020 12:28 |
| PC Close Date & Time | 20 AUG 2020 14:58 |

| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 99.4 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ■<br>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 | 20 AUG 2020 18:56 |
| PC Open Date & Time | 20 AUG 2020 15:53 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ☒<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 98.7 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ☒ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 21 AUG 2020 16:06 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ☒<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 98.6 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ☒ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 22 AUG 2020 16:12 |
| PC Open Date & Time | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

| **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 ☒<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 97.7 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ☒ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 23 AUG 2020 17:15 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ☒<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 99.4 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☒<br>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 | 24 AUG 2020 15:32 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 98.9 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ■<br>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 | 25 AUG 2020 16:48 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 99.6 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ■<br>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 | 26 AUG 2020 17:16 |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 98.8 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ■<br>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 | 27 AUG 2020 19:02 |
| PC Open Date & Time | 27 AUG 2020 12:00 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

| **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 ☐<br>No ☐ |
| Please record your **TEMPERATURE in °F** | _____ |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ☐ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| To **TREAT** pain or fever that has already occurred | _____ |
| To **PREVENT** pain or fever from occurring | _____ |
| PC Time Stamp | _____ |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |

| **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 ☐<br>No ☐ |
| Please record your **TEMPERATURE in °F** | _____ |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ☐ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| To **TREAT** pain or fever that has already occurred | _____ |
| To **PREVENT** pain or fever from occurring | _____ |
| PC Time Stamp | _____ |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |

| **TIMEPOINT** | DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC) |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 20 AUG 2020 12:50 |
| PC Open Date & Time | 20 AUG 2020 12:28 |
| PC Close Date & Time | 20 AUG 2020 14:58 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 1, AFTER VACCINATION (AT HOME) |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ☐<br>Does not interfere with activity ■<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 20 AUG 2020 18:58 |
| PC Open Date & Time | 20 AUG 2020 15:53 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 2 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ☐<br>Does not interfere with activity ■<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 21 AUG 2020 16:07 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 3 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 22 AUG 2020 16:13 |
| PC Open Date & Time | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 4 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 23 AUG 2020 17:16 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 5 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 24 AUG 2020 15:33 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |



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**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 6 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 25 AUG 2020 16:49 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 7 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 26 AUG 2020 17:17 |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

| **TIMEPOINT** | DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC) |
|---|---|
| **HEADACHE** | None ■<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| **FATIGUE** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■<br>Yes ☐ |
| PC Time stamp | 20 AUG 2020 12:51 |
| PC Open Date & Time | 20 AUG 2020 12:28 |
| PC Close Date & Time | 20 AUG 2020 14:58 |

| **TIMEPOINT** | DAY 1, AFTER VACCINATION (AT HOME) |
|---|---|
| **HEADACHE** | None ☐<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ■ |
| **FATIGUE** | None ☐<br>No interference with activity ■<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■<br>Yes ☐ |
| PC Time stamp | 20 AUG 2020 18:57 |
| PC Open Date & Time | 20 AUG 2020 15:53 |
| PC Close Date & Time | 21 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683584

| **TIMEPOINT** | DAY 2 |
|---|---|
| **HEADACHE** | None ☐<br>No interference with activity ■<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| **FATIGUE** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■ |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**

| | Yes |
|---|---|
| PC Time stamp | 21 AUG 2020 16:08 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

| **TIMEPOINT** | DAY 3 |
|---|---|
| **HEADACHE** | None ☐<br>No interference with activity ■<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| **FATIGUE** | None ☐<br>No interference with activity ■<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■ |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**

| | Yes |
|---|---|
| PC Time stamp | 22 AUG 2020 16:14 |
| PC Open Date & Time | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683588

| **TIMEPOINT** | DAY 4 |
|---|---|
| **HEADACHE** | None ☐<br>No interference with activity ■<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| **FATIGUE** | None ☐<br>No interference with activity ■<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■ |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Yes ☐ |
| PC Time stamp | 23 AUG 2020 17:17 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683590

| **TIMEPOINT** | DAY 5 |
|---|---|
| **HEADACHE** | None ☐<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ■ |
| **FATIGUE** | None ☐<br>No interference with activity ☐<br>Some interference with activity ■<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ☐<br>No interference with activity ☐<br>Some interference with activity ■<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■ |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Yes ☐ |
| PC Time stamp | 24 AUG 2020 15:34 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683592

| **TIMEPOINT** | DAY 6 |
|---|---|
| **HEADACHE** | None ☐<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ■<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| **FATIGUE** | None ☐<br>No interference with activity ☐<br>Some interference with activity ■<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■ |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Yes ☐ |
| PC Time stamp | 25 AUG 2020 16:50 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683594

| **TIMEPOINT** | DAY 7 |
|---|---|
| **HEADACHE** | None ☐<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ■<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| **FATIGUE** | None ☐<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ■ |
| **MUSCLE ACHES ALL OVER BODY** | None ☐<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ■ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ☐<br>No interference with activity ■<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ☐<br>No interference with activity or 1-2 episodes/24 hours ■<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■ |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Yes ☐ |
| PC Time stamp | 26 AUG 2020 17:18 |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683596

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 8 |
|---|---|
| Select one response below to indicate the intensity of your **HEADACHE** | None<br>No interference with activity<br>Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity<br>Any use of prescription pain reliever or prevents daily activity |
| PC Time Stamp | 27 AUG 2020 19:03 |
| PC Open Date & Time | 27 AUG 2020 12:00 |
| PC Close Date & Time | 28 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683597

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 9 |
|---|---|
| Select one response below to indicate the intensity of your **HEADACHE** | None ☐<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683598

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 10 |
|---|---|
| Select one response below to indicate the intensity of your **HEADACHE** | None ☐<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683599

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 8 |
|---|---|
| Select one response below to indicate the intensity of your **FATIGUE** | None<br>No interference with activity<br>Some interference with activity<br>Significant; prevents daily activity |
| PC Time Stamp | 27 AUG 2020 19:03 |
| PC Open Date & Time | 27 AUG 2020 12:00 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 9 |
|---|---|
| Select one response below to indicate the intensity of your **FATIGUE** | None ☐<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| PC Time Stamp | |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683601

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| **TIMEPOINT** | DAY 10 |
| Select one response below to indicate the intensity of your **FATIGUE** | None ☐<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| PC Time Stamp | |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683602

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 8 |
|---|---|
| Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY** | None<br>No interference with activity<br>Some interference with activity<br>Significant; prevents daily activity |
| PC Time stamp | 27 AUG 2020 19:03 |
| PC Open Date & Time | 27 AUG 2020 12:00 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 9 |
|---|---|
| Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY** | None ☐<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| PC Time stamp | |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683604

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 10 |
|---|---|
| Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY** | None ☐<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| PC Time stamp | |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683605

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 8 |
|---|---|
| Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS** | None<br>No interference with activity<br>Some interference with activity<br>Significant; prevents daily activity |
| PC Time stamp | 27 AUG 2020 19:03 |
| PC Open Date & Time | 27 AUG 2020 12:00 |
| PC Close Date & Time | 28 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683606

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 9 |
|---|---|
| Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS** | None ☐<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| PC Time stamp | |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683607

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 10 |
|---|---|
| Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS** | None ☐<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| PC Time stamp | |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683608

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 8 |
|---|---|
| Select one response below to indicate the level of your **NAUSEA/VOMITING** | None ☐<br>No interference with activity or 1-2 episodes/24 hours ■<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| PC Time stamp | 27 AUG 2020 19:04 |
| PC Open Date & Time | 27 AUG 2020 12:00 |
| PC Close Date & Time | 28 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683609

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 9 |
|---|---|
| Select one response below to indicate the level of your **NAUSEA/VOMITING** | None ☐<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| PC Time stamp | |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683610

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 10 |
|---|---|
| Select one response below to indicate the level of your **NAUSEA/VOMITING** | None ☐<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| PC Time stamp | |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683611

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 8 |
|---|---|
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ☐<br>Yes ■ |
| PC Time stamp | 27 AUG 2020 19:04 |
| PC Open Date & Time | 27 AUG 2020 12:00 |
| PC Close Date & Time | 28 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683612

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 9 |
|---|---|
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ☐<br>Yes ☐ |
| PC Time stamp | |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**

| **TIMEPOINT** | DAY 10 |
|---|---|
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ☐<br>Yes ☐ |
| PC Time stamp | |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |



FDA-CBER-2022-1614-1683614

**US3292241**
**Folder: Safety Call Day 8 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was Contact Attempted? | Yes ☐<br>No ■ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | |
| Please select one status for the follow-up contact | Contact Made ☐<br>Contact Not Made ☐ |
| Comments<br>*If Contact Not Made, please provide Comments* | SUBJECT WAS IN THE CONVALESCENT PERIOD. |

**US3292241**
**Folder: Safety Call Day 8 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-1683616

**US3292241**
**Folder: Safety Call Day 15 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was Contact Attempted? | Yes ☐<br>No ■ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | |
| Please select one status for the follow-up contact | Contact Made ☐<br>Contact Not Made ☐ |
| Comments<br>*If Contact Not Made, please provide Comments* | SUBJECT WAS IN THE CONVALESCENT PERIOD. |

**US3292241**
**Folder: Safety Call Day 15 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-1683618

**US3292241**
**Folder: Safety Call Day 22 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was Contact Attempted? | Yes ☐<br>No ■ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | |
| Please select one status for the follow-up contact | Contact Made ☐<br>Contact Not Made ☐ |
| Comments<br>*If Contact Not Made, please provide Comments* | SUBJECT WAS IN THE CONVALESCENT PERIOD. |



FDA-CBER-2022-1614-1683619

**US3292241**
**Folder: Safety Call Day 22 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-1683620

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Visit Date**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was this visit performed? | Yes ☒<br>No ☐ |
| Visit date (dd MMM yyyy) | 24 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ☒ |
| Folder OID | VISIT2 |



FDA-CBER-2022-1614-1683621

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Timepoint | Pre-Dose ■<br>Post-Dose ☐ |
| Were vital signs assessed? | Yes ■<br>No ☐ |
| Date of assessment *(dd MMM yyyy)* | 24 SEP 2020 |
| Time of assessment *(00:00-23:59)* | 12:05 (24 HR) |
| Vital Signs Date and Time (derived) | 24 SEP 2020 12:05 |
| Temperature *(xxx.x)* | 37.6 C |
| Route of measurement | Oral ■<br>Axillary ☐<br>Other ☐ |
| If Other, specify | |
| Pulse *(xxx)* | 85 beats/min |
| Pulse units | BPM |
| Respiratory Rate *(xxx)* | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure *(xxx)* | 142 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure *(xxx)* | 98 mmHg |
| Diastolic Blood Pressure units | MMHG |



FDA-CBER-2022-1614-1683622

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Timepoint | Pre-Dose ☐<br>Post-Dose ■ |
| Were vital signs assessed? | Yes ☐<br>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 ☐<br>Axillary ☐<br>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 | |



FDA-CBER-2022-1614-1683623

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Physical Examination**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was the physical examination performed? | Yes ■<br>No ☐ |
| Date of examination *(dd MMM yyyy)* | 24 SEP 2020 |

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



FDA-CBER-2022-1614-1683624

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was study treatment given? | Yes ☐<br>No ■ |
| If No, reason not given | Participant declined due to Adverse Event ■<br>Physician withheld dose due to Adverse Event ☐<br>Death ☐<br>Lost To Follow-Up ☐<br>Physician Decision ☐<br>Pregnancy ☐<br>Protocol Deviation ☐<br>Study Terminated by Sponsor ☐<br>Withdrawal of Consent by Participant ☐<br>Confirmed COVID-19 ☐<br>Other ☐ |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify | SUBJECT DEVELOPED LYMPHADENITIS THEREFORE WITHDREW FROM STUDY |
| What was the study treatment? | |
| What was the treatment date? *(dd MMM yyyy)* | |
| What was the treatment time? *(00:00-23:59)* | |
| Treatment Date and Time (derived) | |
| Which arm was used to give treatment? | Left Arm ☐<br>Right Arm ☐ |
| What was the frequency of the study treatment dosing? | |
| What was the route of administration for the study treatment? | |



FDA-CBER-2022-1614-1683625

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Immunogenicity Assessment**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was the sample collected? | Yes ■<br>No ☐ |
| Collection date *(dd MMM yyyy)* | 24 SEP 2020 |
| Collection time *(00:00-23:59)* | 12:28 (24 HR) |
| Collection date and time (derived) | 24 SEP 2020 12:28 |



FDA-CBER-2022-1614-1683626

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

| Collection date *(dd MMM yyyy)* | | | 24 SEP 2020 |
|---|---|---|---|
| Lab Test | Was the sample collected? | Collection time *(00:00 - 23:59)* | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 13:02 | 24 SEP 2020 13:02 |
| Nasopharyngeal Swab 2 | No | | |



FDA-CBER-2022-1614-1683627

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-1683628

**US3292241**
**Folder: Safety Call Day 36 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was Contact Attempted? | Yes ■<br>No ☐ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 1 OCT 2020 |
| Please select one status for the follow-up contact | Contact Made ■<br>Contact Not Made ☐ |
| Comments<br><br>*If Contact Not Made, please provide Comments* | |



FDA-CBER-2022-1614-1683629

**US3292241**
**Folder: Safety Call Day 36 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-1683630

**US3292241**
**Folder: Safety Call Day 43 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was Contact Attempted? | Yes ■<br>No ☐ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 8 OCT 2020 |
| Please select one status for the follow-up contact | Contact Made ■<br>Contact Not Made ☐ |
| Comments<br><br>*If Contact Not Made, please provide Comments* | |



FDA-CBER-2022-1614-1683631

**US3292241**
**Folder: Safety Call Day 43 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-1683632

**US3292241**
**Folder: Safety Call Day 50 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was Contact Attempted? | Yes ■<br>No ☐ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 15 OCT 2020 |
| Please select one status for the follow-up contact | Contact Made ■<br>Contact Not Made ☐ |
| Comments<br><br>*If Contact Not Made, please provide Comments* | |

**US3292241**
**Folder: Safety Call Day 50 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-1683634

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Visit Date**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was this visit performed? | Yes ■<br>No ☐ |
| Visit date (dd MMM yyyy) | 27 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ■ |
| Folder OID | VISIT3 |



FDA-CBER-2022-1614-1683635

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Were vital signs assessed? | Yes ■<br>No ☐ |
| Date of assessment *(dd MMM yyyy)* | 27 OCT 2020 |
| Time of assessment *(00:00-23:59)* | 11:09 (24 HR) |
| Vital Signs Date and Time (derived) | 27 OCT 2020 11:09 |
| Temperature *(xxx.x)* | 37.3 C |
| Route of measurement | Oral ■<br>Axillary ☐<br>Other ☐ |
| If Other, specify | |
| Pulse *(xxx)* | 86 beats/min |
| Pulse units | BPM |
| Respiratory Rate *(xxx)* | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure *(xxx)* | 129 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure *(xxx)* | 91 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |



FDA-CBER-2022-1614-1683636

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Physical Examination**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

Was the physical examination performed? Yes ☐ No ☒

Date of examination *(dd MMM yyyy)* _____

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



FDA-CBER-2022-1614-1683637

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Immunogenicity Assessment**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was the sample collected? | Yes ■<br>No ☐ |
| Collection date *(dd MMM yyyy)* | 27 OCT 2020 |
| Collection time *(00:00-23:59)* | 11:39 (24 HR) |
| Collection date and time (derived) | 27 OCT 2020 11:39 |



FDA-CBER-2022-1614-1683638

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **22 Feb 2021 21:17:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-1683639

| **TIMEPOINT** | DAY 64 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ☐ Yes ☐ |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No ☐ Yes ☐ |
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 ≥ 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 ☐ |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately ☐ |
| Date and time of submission | |
| Patient Cloud Open Date & Time | 20 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 24 OCT 2020 23:59 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ■<br>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 ■<br>Yes ☐ |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 28 OCT 2020 13:17:30 |
| Patient Cloud Open Date & Time | 27 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 31 OCT 2020 23:59 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ☐<br>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 ■<br>Yes ☐ |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No ■<br>Yes ☐ |
| 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 ☐<br>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 ■ |
| Date and time of submission | 04 NOV 2020 14:03:22 |
| Patient Cloud Open Date & Time | 03 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 07 NOV 2020 23:59 |

| **TIMEPOINT** | DAY 92 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ☐ Yes ☐ |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No ☐ Yes ☐ |
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 ≥ 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 ☐ |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately ☐ |
| Date and time of submission | |
| Patient Cloud Open Date & Time | 17 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 21 NOV 2020 23:59 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ■<br>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 ■<br>Yes ☐ |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 24 NOV 2020 14:24:02 |
| Patient Cloud Open Date & Time | 21 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 25 NOV 2020 23:59 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ☐<br>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 ■<br>Yes ☐ |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No ■<br>Yes ☐ |
| 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 ☐<br>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 ■ |
| Date and time of submission | 02 DEC 2020 10:30:18 |
| Patient Cloud Open Date & Time | 28 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 02 DEC 2020 23:59 |

| **TIMEPOINT** | DAY 110 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ☐ 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 ≥ 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 ☐ |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately ☐ |
| Date and time of submission | |
| Patient Cloud Open Date & Time | 05 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 09 DEC 2020 23:59 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ■<br>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 ■<br>Yes ☐ |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 12 DEC 2020 10:04:05 |
| Patient Cloud Open Date & Time | 12 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 16 DEC 2020 23:59 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ■<br>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 ■<br>Yes ☐ |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 19 DEC 2020 08:19:33 |
| Patient Cloud Open Date & Time | 19 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 23 DEC 2020 23:59 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ☐<br>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 ■<br>Yes ☐ |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No ■<br>Yes ☐ |
| 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 ■<br>Yes ☐ |
| Date and time of submission | 28 DEC 2020 09:41:10 |
| Patient Cloud Open Date & Time | 26 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 30 DEC 2020 23:59 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

| **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 ■<br>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 ■<br>Yes ☐ |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 11 JAN 2021 09:46:01 |
| Patient Cloud Open Date & Time | 09 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 13 JAN 2021 23:59 |

**US3292241**
**Folder: Cosmetic Injections and Dermal Fillers**
**Form: Cosmetic Injection_ Dermal Filler eDiary**
**Generated On: 11 Aug 2021 22:21:07**

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



FDA-CBER-2022-1614-1683654

**US3292241**
**Folder: Safety Call Day 85 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was Contact Attempted? | Yes ■<br>No ☐ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 19 NOV 2020 |
| Please select one status for the follow-up contact | Contact Made ■<br>Contact Not Made ☐ |
| Comments<br><br>*If Contact Not Made, please provide Comments* | |

**US3292241**
**Folder: Safety Call Day 85 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-1683656

**US3292241**
**Folder: Safety Call Day 119 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was Contact Attempted? | Yes ■<br>No ☐ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 23 DEC 2020 |
| Please select one status for the follow-up contact | Contact Made ■<br>Contact Not Made ☐ |
| Comments<br><br>*If Contact Not Made, please provide Comments* | |

**US3292241**
**Folder: Safety Call Day 119 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-1683658

**US3292241**
**Folder: Safety Call Day 149 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was Contact Attempted? | Yes ☐<br>No ☐ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | |
| Please select one status for the follow-up contact | Contact Made ☐<br>Contact Not Made ☐ |
| Comments<br><br>*If Contact Not Made, please provide Comments* | |

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ☐<br>No ☐ |
| Continuing Flag | _____ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID-19 Contact**
**Data signed:** (b) (4) **22 Feb 2021 21:16:57**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Date of Contact | 27 AUG 2020 |
| Time of Contact | 13:05 |
| Date and Time of Contact (derived) | 27 AUG 2020 13:05 |
| Type of Contact | Clinic Visit - Scheduled ☐<br>Clinical Visit - Unscheduled ■<br>Safety Call ☐<br>Convalescent Tele-visit ☐ |
| Has the subject reported symptoms of SARS-COV-2? | Yes ■<br>No ☐ |



FDA-CBER-2022-1614-1683661

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| Symptom Day | |
|---|---|
| | Day 1 |
| | Day 2 |
| | Day 3 |
| | Day 4 |
| | Day 5 |
| | Day 6 |
| | Day 7 |
| | Day 8 |
| | Day 9 |
| | Day 10 |
| | Day 11 |
| | Day 12 |
| | Day 13 |
| | Day 14 |
| | Day 15 |
| | Day 16 |
| | Day 17 |
| | Day 18 |
| | Day 19 |
| | Day 20 |
| | Day 21 |
| | Day 22 |
| | Day 23 |
| | Day 24 |
| | Day 25 |
| | Day 26 |
| | Day 27 |
| | Day 28 |
| | Day 29 |
| | Day 30 |
| | Day 31 |
| | Day 32 |



FDA-CBER-2022-1614-1683662

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 28 AUG 2020 |
| Assessment Not Done | False |
| O2 Saturation | 98 % |
| O2 Saturation Units | % |
| Temperature | 37.1 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| Symptom Day | |
|---|---|
| | Day 1 ☐ |
| | Day 2 ☐ |
| | Day 3 ■ |
| | Day 4 ☐ |
| | Day 5 ☐ |
| | Day 6 ☐ |
| | Day 7 ☐ |
| | Day 8 ☐ |
| | Day 9 ☐ |
| | Day 10 ☐ |
| | Day 11 ☐ |
| | Day 12 ☐ |
| | Day 13 ☐ |
| | Day 14 ☐ |
| | Day 15 ☐ |
| | Day 16 ☐ |
| | Day 17 ☐ |
| | Day 18 ☐ |
| | Day 19 ☐ |
| | Day 20 ☐ |
| | Day 21 ☐ |
| | Day 22 ☐ |
| | Day 23 ☐ |
| | Day 24 ☐ |
| | Day 25 ☐ |
| | Day 26 ☐ |
| | Day 27 ☐ |
| | Day 28 ☐ |
| | Day 29 ☐ |
| | Day 30 ☐ |
| | Day 31 ☐ |
| | Day 32 ☐ |

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 29 AUG 2020 |
| Assessment Not Done | False |
| O2 Saturation | 96 % |
| O2 Saturation Units | % |
| Temperature | 35.7 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 30 AUG 2020 |
| Assessment Not Done | False |
| O2 Saturation | 98 % |
| O2 Saturation Units | % |
| Temperature | 37.1 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 31 AUG 2020 |
| Assessment Not Done | False |
| O2 Saturation | 98 % |
| O2 Saturation Units | % |
| Temperature | 37.2 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32



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| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 1 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 100 % |
| O2 Saturation Units | % |
| Temperature | 37.6 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 2 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 96 % |
| O2 Saturation Units | % |
| Temperature | 36.8 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| Symptom Day | |
|---|---|
| | Day 1 |
| | Day 2 |
| | Day 3 |
| | Day 4 |
| | Day 5 |
| | Day 6 |
| | Day 7 |
| | Day 8 |
| | Day 9 |
| | Day 10 |
| | Day 11 |
| | Day 12 |
| | Day 13 |
| | Day 14 |
| | Day 15 |
| | Day 16 |
| | Day 17 |
| | Day 18 |
| | Day 19 |
| | Day 20 |
| | Day 21 |
| | Day 22 |
| | Day 23 |
| | Day 24 |
| | Day 25 |
| | Day 26 |
| | Day 27 |
| | Day 28 |
| | Day 29 |
| | Day 30 |
| | Day 31 |
| | Day 32 |



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| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 3 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 96 % |
| O2 Saturation Units | % |
| Temperature | 37.6 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32



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| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 4 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 98 % |
| O2 Saturation Units | % |
| Temperature | 36.4 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 5 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 97 % |
| O2 Saturation Units | % |
| Temperature | 36.8 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 6 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 97 % |
| O2 Saturation Units | % |
| Temperature | 37.1 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 7 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 97 % |
| O2 Saturation Units | % |
| Temperature | 36.8 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 8 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 97 % |
| O2 Saturation Units | % |
| Temperature | 36.4 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 9 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 98 % |
| O2 Saturation Units | % |
| Temperature | 36.9 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 10 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 97 % |
| O2 Saturation Units | % |
| Temperature | 37.0 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32



FDA-CBER-2022-1614-1683718

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 11 SEP 2020 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Runny Nose (Rhinorrhea) | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Nausea | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Vomiting | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Diarrhea | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Sore Throat | None<br>Mild<br>Moderate<br>Severe<br>Not Done |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| Symptom Day | |
|---|---|
| | Day 1 |
| | Day 2 |
| | Day 3 |
| | Day 4 |
| | Day 5 |
| | Day 6 |
| | Day 7 |
| | Day 8 |
| | Day 9 |
| | Day 10 |
| | Day 11 |
| | Day 12 |
| | Day 13 |
| | Day 14 |
| | Day 15 |
| | Day 16 |
| | Day 17 |
| | Day 18 |
| | Day 19 |
| | Day 20 |
| | Day 21 |
| | Day 22 |
| | Day 23 |
| | Day 24 |
| | Day 25 |
| | Day 26 |
| | Day 27 |
| | Day 28 |
| | Day 29 |
| | Day 30 |
| | Day 31 |
| | Day 32 |

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 12 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 97 % |
| O2 Saturation Units | % |
| Temperature | 36.8 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 13 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 100 % |
| O2 Saturation Units | % |
| Temperature | 36.7 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32



FDA-CBER-2022-1614-1683730

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 14 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 97 % |
| O2 Saturation Units | % |
| Temperature | 37.1 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 15 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 97 % |
| O2 Saturation Units | % |
| Temperature | 36.0 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 16 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 94 % |
| O2 Saturation Units | % |
| Temperature | 37.0 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 17 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 97 % |
| O2 Saturation Units | % |
| Temperature | 36.8 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32



FDA-CBER-2022-1614-1683746

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 18 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 98 % |
| O2 Saturation Units | % |
| Temperature | 36.2 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| Symptom Day | |
|---|---|
| | Day 1 |
| | Day 2 |
| | Day 3 |
| | Day 4 |
| | Day 5 |
| | Day 6 |
| | Day 7 |
| | Day 8 |
| | Day 9 |
| | Day 10 |
| | Day 11 |
| | Day 12 |
| | Day 13 |
| | Day 14 |
| | Day 15 |
| | Day 16 |
| | Day 17 |
| | Day 18 |
| | Day 19 |
| | Day 20 |
| | Day 21 |
| | Day 22 |
| | Day 23 |
| | Day 24 |
| | Day 25 |
| | Day 26 |
| | Day 27 |
| | Day 28 |
| | Day 29 |
| | Day 30 |
| | Day 31 |
| | Day 32 |



FDA-CBER-2022-1614-1683750

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 27 AUG 2020 |
| Assessment Not Done | False |
| O2 Saturation | 98 % |
| O2 Saturation Units | % |
| Temperature | 37.0 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ☐<br>Mild ☐<br>Moderate ■<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32



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| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 19 SEP 2020 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Runny Nose (Rhinorrhea) | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Nausea | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Vomiting | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Diarrhea | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Sore Throat | None<br>Mild<br>Moderate<br>Severe<br>Not Done |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32



FDA-CBER-2022-1614-1683758

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 21 SEP 2020 |
| Assessment Not Done | False |
| O2 Saturation | 97 % |
| O2 Saturation Units | % |
| Temperature | 36.4 C |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32



FDA-CBER-2022-1614-1683762

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 20 SEP 2020 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Runny Nose (Rhinorrhea) | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Nausea | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Vomiting | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Diarrhea | None<br>Mild<br>Moderate<br>Severe<br>Not Done |
| Sore Throat | None<br>Mild<br>Moderate<br>Severe<br>Not Done |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID Diagnostic Test**
**Data signed:** (b) (4) **22 Feb 2021 21:16:56**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Date of Visit | 27 AUG 2020 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes ■<br>No ☐ |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes ☐<br>No ☐ |
| Date of Test | 27 AUG 2020 |
| Type of Test Performed | Nasopharyngeal Swab ■<br>Nasal Swab ☐<br>Saliva Test ☐<br>Other ☐ |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes ☐<br>No ■ |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | |
| CLIA Certified? | Yes ☐<br>No ☐ |
| COVID-19 Positive (CSA Programming Field Only) | |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Generate Next COVID-19 Assessment**
**Data signed:** (b) (4) **22 Feb 2021 21:16:57**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Generate Next COVID-19 Assessment | Yes ☐<br>No ■ |



FDA-CBER-2022-1614-1683767

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| Visit | Was Saliva Collected? | Date of Collection |
|---|---|---|
| Day 3 | Yes | 29 AUG 2020 |
| Day 5 | Yes | 31 AUG 2020 |
| Day 7 | Yes | 02 SEP 2020 |
| Day 9 | Yes | 04 SEP 2020 |
| Day 14 | Yes | 09 SEP 2020 |
| Day 21 | Yes | 16 SEP 2020 |
| Day 28 | No | |



FDA-CBER-2022-1614-1683768

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Visit Date**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was this visit performed? | Yes ■<br>No ☐ |
| Visit date (dd MMM yyyy) | 27 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home ■<br>Clinic ☐ |
| Folder OID | SICKD1 |



FDA-CBER-2022-1614-1683769

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Were vital signs assessed? | Yes ■<br>No ☐ |
| Date of assessment *(dd MMM yyyy)* | 27 AUG 2020 |
| Time of assessment *(00:00-23:59)* | 13:05 (24 HR) |
| Vital Signs Date and Time (derived) | 27 AUG 2020 13:05 |
| Height *(xxx.x)* | 167.6 cm |
| Weight *(xxx.x)* | 141.2 kg |
| Temperature *(xxx.x)* | 37.0 C |
| Route of measurement | Oral ■<br>Axillary ☐<br>Other ☐ |
| If Other, specify | |
| Pulse *(xxx)* | 74 beats/min |
| Pulse units | BPM |
| Respiratory Rate *(xxx)* | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure *(xxx)* | 145 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure *(xxx)* | 79 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Physical Examination**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was the physical examination performed? | Yes ■<br>No ☐ |
| Date of examination *(dd MMM yyyy)* | 27 AUG 2020 |

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

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**
**Data signed:** (b) (4) **22 Feb 2021 21:17:01**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection? | Yes ■<br>No ☐<br>NA (COVID-19 Negative) ☐ |
| Date of Collection | 27 AUG 2020 |



FDA-CBER-2022-1614-1683772

**US3292241**
**Folder: Convalescence Visit Day 28 (1)**
**Form: Visit Date**
**Data signed:** (b) (4) **22 Feb 2021 21:16:56**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was this visit performed? | Yes ☐<br>No ■ |
| Visit date (dd MMM yyyy) | |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ☐ |
| Folder OID | SICKD28 |



FDA-CBER-2022-1614-1683773

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Visit Date**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was this visit performed? | Yes ☐<br>No ■ |
| Visit date (dd MMM yyyy) | |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ☐ |
| Folder OID | UNBLND_DECIDE |



FDA-CBER-2022-1614-1683774

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Date of updated informed consent *(dd MMM yyyy)* | |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | True |
| Was the participant unblinded? | Yes ■<br>No ☐ |
| Under what version of the Protocol was the Participant unblinded? | Amendment 5 ■<br>Amendment 6 or later ☐ |
| Date of unblinding *(dd MMM yyyy)* | 31 DEC 2020 |
| Participant randomization assignment | mRNA-1273 ■<br>Placebo ☐ |
| Actual Dose 1 | mRNA-1273 ■<br>Placebo ☐<br>Not Administered ☐ |
| Actual Dose 2 | mRNA-1273 ☐<br>Placebo ☐<br>Not Administered ■ |
| Will participant receive mRNA-1273? | Yes ☐<br>No ■ |
| Placebo Only Flag | |
| Continuing with mRNA-1273 | |



FDA-CBER-2022-1614-1683775

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Immunogenicity Assessment**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was the sample collected? | Yes ☐<br>No ■ |
| Collection date *(dd MMM yyyy)* | |
| Collection time *(00:00-23:59)* | |
| Collection date and time (derived) | |



FDA-CBER-2022-1614-1683776

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (Single)**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Was the sample collected? | Yes ☐<br>No ■ |
| Collection date *(dd MMM yyyy)* | |
| Collection time *(00:00 - 23:59)* | |
| Collection Date and Time (derived) | |



FDA-CBER-2022-1614-1683777

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events Summary**
**Data signed:** (b) (4) **16 Apr 2021 14:19:03**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Did the participant experience any adverse events? | Yes ■<br>No ☐ |

**If Yes, enter details on the Adverse Events form.**



FDA-CBER-2022-1614-1683778

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Data signed:** (b) (4) **28 Apr 2021 13:37:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| AEID | |
| Adverse event | BILATERAL LYMPHADENITIS (NECK) |
| Was this a medically-attended AE? | Yes ☐<br>No ■ |
| Was this a Solicited Adverse Reaction? | Yes ☐<br>No ■ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ☐<br>No ■ |
| Start date *(dd MMM yyyy)* | 21 AUG 2020 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 27 OCT 2020 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ☐<br>Grade 2/Moderate ■<br>Grade 3/Severe ☐<br>Grade 4 ☐ |
| Is the adverse event serious? | Yes ☐<br>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 ☐<br>No ☐<br>Unknown ☐ |

| | |
|---|---|
| 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 ☐<br>Related ■<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ☐<br>Dose Delayed ☐<br>Investigational Product Withdrawn ☐<br>Not Applicable ■ |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal ☐<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ■<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Ony) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Data signed:** (b) (4) **28 Apr 2021 13:37:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| AEID | |
| Adverse event | LEFT EYE SWELLING |
| Was this a medically-attended AE? | Yes ☐<br>No ■ |
| Was this a Solicited Adverse Reaction? | Yes ☐<br>No ■ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ☐<br>No ■ |
| Start date *(dd MMM yyyy)* | 21 AUG 2020 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 12 NOV 2020 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ■<br>Grade 2/Moderate ☐<br>Grade 3/Severe ☐<br>Grade 4 ☐ |
| Is the adverse event serious? | Yes ☐<br>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 ☐<br>No ☐<br>Unknown ☐ |
| 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 ■<br>Related ☐<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ■<br>Dose Delayed ☐<br>Investigational Product Withdrawn ☐<br>Not Applicable ☐ |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal ☐<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ■<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Ony) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Data signed:** (b) (4) **28 Apr 2021 13:37:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| AEID | |
| Adverse event | OCCIPITAL HEADACHE |
| Was this a medically-attended AE? | Yes ☐<br>No ■ |
| Was this a Solicited Adverse Reaction? | Yes ■<br>No ☐ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ☐<br>No ■ |
| Start date *(dd MMM yyyy)* | 20 AUG 2020 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 30 SEP 2020 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ☐<br>Grade 2/Moderate ■<br>Grade 3/Severe ☐<br>Grade 4 ☐ |
| Is the adverse event serious? | Yes ☐<br>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 ☐<br>No ☐<br>Unknown ☐ |
| 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 ☐<br>Related ■<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ☐<br>Dose Delayed ☐<br>Investigational Product Withdrawn ■<br>Not Applicable ☐ |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal ☐<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ■<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Ony) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Data signed:** (b) (4) **28 Apr 2021 13:37:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| AEID | |
| Adverse event | FATIGUE |
| Was this a medically-attended AE? | Yes ☐<br>No ■ |
| Was this a Solicited Adverse Reaction? | Yes ■<br>No ☐ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ☐<br>No ■ |
| Start date *(dd MMM yyyy)* | 20 AUG 2020 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 21 SEP 2020 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ■<br>Grade 2/Moderate ☐<br>Grade 3/Severe ☐<br>Grade 4 ☐ |
| Is the adverse event serious? | Yes ☐<br>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 ☐<br>No ☐<br>Unknown ☐ |
| 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 ☐<br>Related ■<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ☐<br>Dose Delayed ☐<br>Investigational Product Withdrawn ☐<br>Not Applicable ■ |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal ☐<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ■<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Ony) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Data signed:** (b) (4) **28 Apr 2021 13:37:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| AEID | |
| Adverse event | ABDOMINAL PAIN |
| Was this a medically-attended AE? | Yes ■<br>No ☐ |
| Was this a Solicited Adverse Reaction? | Yes ☐<br>No ■ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ☐<br>No ■ |
| Start date *(dd MMM yyyy)* | 24 NOV 2020 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 16 DEC 2020 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ☐<br>Grade 2/Moderate ■<br>Grade 3/Severe ☐<br>Grade 4 ☐ |
| Is the adverse event serious? | Yes ☐<br>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 ☐<br>No ☐<br>Unknown ☐ |
| 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 ■<br>Related ☐<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ■<br>Dose Delayed ☐<br>Investigational Product Withdrawn ☐<br>Not Applicable ☐ |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal ☐<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ■<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Ony) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Data signed:** (b) (4) **28 Apr 2021 13:37:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| AEID | |
| Adverse event | HEADACHE - REACTOGENICITY |
| Was this a medically-attended AE? | Yes ☐<br>No ■ |
| Was this a Solicited Adverse Reaction? | Yes ■<br>No ☐ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ☐<br>No ■ |
| Start date *(dd MMM yyyy)* | 20 AUG 2020 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 27 AUG 2020 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ☐<br>Grade 2/Moderate ■<br>Grade 3/Severe ☐<br>Grade 4 ☐ |
| Is the adverse event serious? | Yes ☐<br>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 ☐<br>No ☐<br>Unknown ☐ |
| 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 ☐<br>Related ■<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ■<br>Dose Delayed ☐<br>Investigational Product Withdrawn ☐<br>Not Applicable ☐ |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal ☐<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ■<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | SINCE SAR OCCURRED BEYOND 7 DAYS POST DOSE, THIS IS NOW RECORDED AS AE. |
| Serious Adverse Event Derived (CSA Programming Field Ony) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Data signed:** (b) (4) **28 Apr 2021 13:37:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| AEID | |
| Adverse event | JOINT ACHES IN SEVERAL JOINTS - REACTOGENICITY |
| Was this a medically-attended AE? | Yes ☐<br>No ■ |
| Was this a Solicited Adverse Reaction? | Yes ■<br>No ☐ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ☐<br>No ■ |
| Start date *(dd MMM yyyy)* | 26 AUG 2020 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 27 AUG 2020 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ☐<br>Grade 2/Moderate ■<br>Grade 3/Severe ☐<br>Grade 4 ☐ |
| Is the adverse event serious? | Yes ☐<br>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 ☐<br>No ☐<br>Unknown ☐ |

| | |
|---|---|
| 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 ☐<br>Related ■<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ■<br>Dose Delayed ☐<br>Investigational Product Withdrawn ☐<br>Not Applicable ☐ |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal ☐<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ■<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | SINCE SAR OCCURRED BEYOND 7 DAYS POST DOSE, THIS IS NOW RECORDED AS AE |
| Serious Adverse Event Derived (CSA Programming Field Ony) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Data signed:** (b) (4) **28 Apr 2021 13:37:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| AEID | |
| Adverse event | MUSCLE ACHES ALL OVER BODY - REACTOGENICITY |
| Was this a medically-attended AE? | Yes ☐<br>No ■ |
| Was this a Solicited Adverse Reaction? | Yes ■<br>No ☐ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ☐<br>No ■ |
| Start date *(dd MMM yyyy)* | 24 AUG 2020 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 27 AUG 2020 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ☐<br>Grade 2/Moderate ■<br>Grade 3/Severe ☐<br>Grade 4 ☐ |
| Is the adverse event serious? | Yes ☐<br>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 ☐<br>No ☐<br>Unknown ☐ |

| | |
|---|---|
| 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 ☐<br>Related ■<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ■<br>Dose Delayed ☐<br>Investigational Product Withdrawn ☐<br>Not Applicable ☐ |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal ☐<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ■<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | SINCE SAR OCCURRED BEYOND 7 DAYS POST DOSE, THIS IS NOW RECORDED AS AE |
| Serious Adverse Event Derived (CSA Programming Field Ony) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Data signed:** (b) (4) **28 Apr 2021 13:37:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| AEID | |
| Adverse event | NAUSEA - REACTOGENICITY |
| Was this a medically-attended AE? | Yes ☐<br>No ■ |
| Was this a Solicited Adverse Reaction? | Yes ■<br>No ☐ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ☐<br>No ■ |
| Start date *(dd MMM yyyy)* | 26 AUG 2020 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 27 AUG 2020 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ☐<br>Grade 2/Moderate ■<br>Grade 3/Severe ☐<br>Grade 4 ☐ |
| Is the adverse event serious? | Yes ☐<br>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 ☐<br>No ☐<br>Unknown ☐ |
| 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 ☐<br>Related ■<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ■<br>Dose Delayed ☐<br>Investigational Product Withdrawn ☐<br>Not Applicable ☐ |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal ☐<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ■<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | SINCE SAR OCCURRED BEYOND 7 DAYS POST DOSE, THIS IS NOW RECORDED AS AE |
| Serious Adverse Event Derived (CSA Programming Field Ony) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Data signed:** (b) (4) **28 Apr 2021 13:37:31**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| AEID | |
| Adverse event | VOMITING - REACTOGENICITY |
| Was this a medically-attended AE? | Yes ☐<br>No ■ |
| Was this a Solicited Adverse Reaction? | Yes ■<br>No ☐ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ☐<br>No ■ |
| Start date *(dd MMM yyyy)* | 26 AUG 2020 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 27 AUG 2020 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ☐<br>Grade 2/Moderate ■<br>Grade 3/Severe ☐<br>Grade 4 ☐ |
| Is the adverse event serious? | Yes ☐<br>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 ☐<br>No ☐<br>Unknown ☐ |
| 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 ☐<br>Related ■<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ■<br>Dose Delayed ☐<br>Investigational Product Withdrawn ☐<br>Not Applicable ☐ |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal ☐<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ■<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Ony) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination Summary**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Were any prior/concomitant medications and/or vaccinations taken? | Yes ■<br>No ☐ |

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



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**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

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

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 1960 |
| Start date completely unknown | False |
| Ongoing? | Yes ■ |
| | No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Name of Medication | QUERCETIN |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | SEASONAL ALLERGIES |
| Dose per administration | 1 |
| Dose unit | mg ☐<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ■<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |



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| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2000 |
| Start date completely unknown | False |
| Ongoing? | Yes ■ |
| | No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Name of Medication | MELATONIN |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | INSOMNIA |
| Dose per administration | 3 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ■<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2015 |
| Start date completely unknown | False |
| Ongoing? | Yes ■<br>No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ☐ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Name of Medication | REFRESH PLUS EYE DROPS |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | DRY EYES |
| Dose per administration | 2 |
| Dose unit | mg ☐<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ■ |
| If dose unit is Other, specify | DROPS |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ■<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ■ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2000 |
| Start date completely unknown | False |
| Ongoing? | Yes ■ |
| | No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ☐ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Name of Medication | FIBER |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | CONSTIPATION |
| Dose per administration | 1 |
| Dose unit | mg ☐<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ■<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ■<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2000 |
| Start date completely unknown | False |
| Ongoing? | Yes ■ |
| | No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ☐ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
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| | |
|---|---|
| Name of Medication | TELMISARTAN |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | HYPERTENSION |
| Dose per administration | 5 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN JAN 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ■<br>No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ■ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Name of Medication | MONTELUKAST |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | SEASONAL ALLERGIES |
| Dose per administration | 5 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ■<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2017 |
| Start date completely unknown | False |
| Ongoing? | Yes ■ |
| | No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ☐ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Name of Medication | NASACORT |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | SEASONAL ALLERGIES |
| Dose per administration | 220 |
| Dose unit | mg ☐<br>ug ■<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ■<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ■ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2010 |
| Start date completely unknown | False |
| Ongoing? | Yes ■ |
| | No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ☐ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Name of Medication | NATURE THYROID |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | HYPOTHYROIDISM |
| Dose per administration | 48.75 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2001 |
| Start date completely unknown | False |
| Ongoing? | Yes ■ |
| | No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
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| | |
|---|---|
| Name of Medication | ZOLPIDEM |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | INSOMNIA |
| Dose per administration | 5 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ■<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2015 |
| Start date completely unknown | False |
| Ongoing? | Yes ■<br>No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ☐ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
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| | |
|---|---|
| Name of Medication | ESTROGEN |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | HORMONE REPLACEMENT |
| Dose per administration | 1 |
| Dose unit | mg ☐<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ■ |
| If dose unit is Other, specify | APPLICATION |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ■<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |



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| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2000 |
| Start date completely unknown | False |
| Ongoing? | Yes ■ |
| | No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
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| | |
|---|---|
| Name of Medication | PROGESTERONE |
| Prophylaxis | Yes<br>No ■ |
| Indication | HORMONE REPLACEMENT |
| Dose per administration | 100 |
| Dose unit | mg ■<br>ug<br>mL<br>g<br>IU<br>tablet<br>capsule<br>puff<br>Other |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily<br>three times daily<br>four times daily<br>every other day<br>every week<br>every month<br>as needed<br>once<br>unknown<br>other |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical<br>Subcutaneous<br>Transdermal<br>Intraocular |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2000 |
| Start date completely unknown | False |
| Ongoing? | Yes ■ |
| | No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Name of Medication | PREDNISOLONE |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | ASTHMA |
| Dose per administration | 10 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ■<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2015 |
| Start date completely unknown | False |
| Ongoing? | Yes ■<br>No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ☐ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
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| | |
|---|---|
| Name of Medication | CLINDAMYCIN |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | BILATERAL LYMPHADENITIS (NECK) |
| Dose per administration | 150 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ■<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐ |

| | |
|---|---|
| | Intraocular ☐ |
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 22 SEP 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 24 SEP 2020 |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ☐ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Name of Medication | INFLUENZA VACINE |
| Prophylaxis | Yes ■<br>No ☐ |
| Indication | PROPHYLAXIS |
| Dose per administration | 1 |
| Dose unit | mg ☐<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ■ |
| If dose unit is Other, specify | INJECTION |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ■<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ■<br>Respiratory (Inhalation) ☐<br>Intralesional ☐<br>Intraperiteoneal ☐<br>Nasal ☐<br>Vaginal ☐<br>Rectal ☐<br>Intravenous ☐<br>Intravenous Bolus ☐<br>Intravenous Drip ☐<br>Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 13 OCT 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 13 OCT 2020 |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ☐ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
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| | |
|---|---|
| Name of Medication | TYLENOL |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | REACTOGENICITY (HEADACHES,FATIGUE) |
| Dose per administration | 500 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐ |

| | |
|---|---|
| | Intraocular ☐ |
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 20 AUG 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 27 AUG 2020 |
| Was this medication taken for solicited event? | Yes ■<br>No ☐ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ■ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
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| | |
|---|---|
| Name of Medication | AMOX/CLAV |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | ABDOMINAL PAIN |
| Dose per administration | 875/175 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ■<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 27 NOV 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 4 DEC 2020 |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | 2 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ■ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Name of Medication | METRONIDAZOLE |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | ABDOMINAL PAIN |
| Dose per administration | 300 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ■<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 27 NOV 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 4 DEC 2020 |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | 2 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ■ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Name of Medication | MODERNA VACCINE |
| Prophylaxis | Yes ■<br>No ☐ |
| Indication | COVID-19 VACCINATION |
| Dose per administration | 0.5 |
| Dose unit | mg ☐<br>ug ☐<br>mL ■<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ■<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ■<br>Respiratory (Inhalation) ☐<br>Intralesional ☐<br>Intraperiteoneal ☐<br>Nasal ☐<br>Vaginal ☐<br>Rectal ☐<br>Intravenous ☐<br>Intravenous Bolus ☐<br>Intravenous Drip ☐<br>Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 24 DEC 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 24 DEC 2020 |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ☐ |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Data signed:** (b) (4) **23 Apr 2021 18:33:21**
**Generated On: 11 Aug 2021 22:21:07**

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

| | |
|---|---|
| | Intramuscular ☐<br>Respiratory (Inhalation) ☐<br>Intralesional ☐<br>Intraperiteoneal ☐<br>Nasal ☐<br>Vaginal ☐<br>Rectal ☐<br>Intravenous ☐<br>Intravenous Bolus ☐<br>Intravenous Drip ☐<br>Other ■ |
| If route of administration is Other, specify | UNKNOWN |
| Start date *(dd MMM yyyy)* | 20 AUG 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 27 AUG 2020 |
| Was this medication taken for solicited event? | Yes ■<br>No ☐ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ☐ |

**US3292241**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures Summary**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Were any concomitant procedures performed? | Yes ■<br>No ☐ |

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



FDA-CBER-2022-1614-1683840

**US3292241**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| Procedure/Surgery date *(dd MMM yyyy)* | Procedure/Surgery | Indication | If indication is Other, specify |
|---|---|---|---|
| 06 NOV 2020 | PUNCTAL PLUGS | Medical History | |



FDA-CBER-2022-1614-1683841

**US3292241**
**Folder: End of Study (1)**
**Form: Dosing Discontinuation**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Date of dosing discontinuation (dd MMM yyyy) | 25 SEP 2020 |
| Primary reason for dosing discontinuation | AE (specify) ■<br>SAE (specify) ☐<br>Death ☐<br>Lost To Follow-up ☐<br>Physician decision (specify) ☐<br>Pregnancy ☐<br>Protocol deviation (specify) ☐<br>Study Terminated By Sponsor ☐<br>Withdrawal of consent by participant (specify) ☐<br>Due to SARS-COV-2 ☐<br>Other ☐ |
| If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify | A TEMPERATURE OF 99.8CONSTANT HEADACHES AND FATIGUE, SWOLLEN LYMPHNODES, SWELLING AND PAIN AROUND THE LEFT EYE (AE#1, AE#2, AE#3, AE#4) |



FDA-CBER-2022-1614-1683842

**US3292241**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Data signed:** (b) (4) **16 Apr 2021 14:19:04**
**Generated On: 11 Aug 2021 22:21:07**

| | |
|---|---|
| Date of study discontinuation/completion *(dd MMM yyyy)* | 31 DEC 2020 |
| Reason for discontinuation | AE (specify) ☐<br>SAE (specify) ☐<br>Complete ☐<br>Death ☐<br>Lost To Follow-up ☐<br>Physician decision (specify) ☐<br>Pregnancy ☐<br>Protocol deviation (specify) ■<br>Study Terminated By Sponsor ☐<br>Withdrawal of consent by participant (specify) ☐<br>Other ☐ |
| If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify | PATIENT RECEIVED EUA VACCINATION OUTSIDE OF STUDY |
| If reason for discontinuation is Death, main cause of death | Adverse event ☐<br>Unknown ☐<br>Other ☐ |
| If main cause of death is Other, specify | |
| Date of death *(dd MMM yyyy)* | |
| Was autopsy performed? | Yes ☐<br>No ☐<br>Unknown ☐ |



FDA-CBER-2022-1614-1683843

Audit

US3292241 (Prod: Clinical Trials of Texas, Inc)

**US3292241**
**Form: Participant Creation**
**Generated On: 11 Aug 2021 22:21:07**
Participant ID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:15:07 |
| User entered 'US3292241' | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 14:24:38 |



FDA-CBER-2022-1614-1683845

**US3292241**
**Form: Participant Creation**
**Generated On: 11 Aug 2021 22:21:07**

mRNA-1273-P301 Completion Guidelines

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1683846

**US3292241**
**Folder: Screening**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was this visit performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:36:09 |
| User closed query 'Please provide eSource' (Site from CRA). | | 10 Feb 2021 19:35:34 |
| Query 'Please provide eSource' answered with 'Should now be available in esource' (Site from CRA). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:48:11 |
| User opened query 'Please provide eSource' (Site from CRA). | (b) (4), (b) (6) | 14 Jan 2021 19:56:01 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:45:03 |



FDA-CBER-2022-1614-1683847

**US3292241**
**Folder: Screening**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:36:09 |
| User entered '20 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 14:24:39 |



FDA-CBER-2022-1614-1683848

**US3292241**
**Folder: Screening**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:36:09 |
| User entered 'Clinic (Clinic)' | | 21 Aug 2020 14:45:03 |



FDA-CBER-2022-1614-1683849

**US3292241**
**Folder: Screening**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Folder OID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'SCRN' | System | 21 Aug 2020 14:45:03 |



FDA-CBER-2022-1614-1683850

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:30 |
| User entered (b) (6) 1953' | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 14:24:40 |



FDA-CBER-2022-1614-1683851

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
Age

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:32 |
| User entered '67' | | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683852

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
Age Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'YEARS' | System | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683853

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
Age (Derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '67' | System | 20 Aug 2020 17:17:28 |



FDA-CBER-2022-1614-1683854

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
Sex

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:47 |
| User entered 'Female (F)' | | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683855

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
Ethnicity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:50 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683856

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
White

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:53 |
| User entered '1' | | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683857

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
Black

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:56 |
| User entered '0' | | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683858

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
Asian

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:56 |
| User entered '0' | | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683859

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
American Indian or Alaska Native

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:56 |
| User entered '0' | | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683860

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
Native Hawaiian or other Pacific Islander

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:56 |
| User entered '0' | | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683861

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
Other

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:56 |
| User entered '0' | | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683862

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
If race is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:56 |
| User entered empty. | | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683863

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
Unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:56 |
| User entered '0' | | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683864

**US3292241**
**Folder: Screening**
**Form: Demographics**
**Generated On: 11 Aug 2021 22:21:07**
Not reported

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:32:56 |
| User entered '0' | | 21 Aug 2020 14:45:33 |



FDA-CBER-2022-1614-1683865

**US3292241**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 11 Aug 2021 22:21:07**
Date of Informed Consent *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:36:18 |
| User entered '20 Aug 2020' | Nathan Cortez (b) (4) | 20 Aug 2020 17:17:28 |



FDA-CBER-2022-1614-1683866

**US3292241**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 11 Aug 2021 22:21:07**
Month and Year of Informed Consent (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Aug 2020' | System | 20 Aug 2020 17:17:28 |



FDA-CBER-2022-1614-1683867

**US3292241**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 11 Aug 2021 22:21:07**
Year of Informed Consent (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2020' | System | 20 Aug 2020 17:17:28 |



FDA-CBER-2022-1614-1683868

**US3292241**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 11 Aug 2021 22:21:07**
Protocol Version

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:36:18 |
| User entered 'Amendment 2 (2)' | Nathan Cortez (b) (4) | 20 Aug 2020 17:17:28 |



FDA-CBER-2022-1614-1683869

**US3292241**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 11 Aug 2021 22:21:07**
Was participant enrolled in the study?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:36:18 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 20 Aug 2020 17:17:28 |

**US3292241**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 11 Aug 2021 22:21:07**
If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:36:18 |
| User entered empty. | Nathan Cortez (b) (4) | 20 Aug 2020 17:17:28 |



FDA-CBER-2022-1614-1683871

**US3292241**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 11 Aug 2021 22:21:07**
If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:36:18 |
| User entered empty. | Nathan Cortez (b) (4) | 20 Aug 2020 17:17:28 |



FDA-CBER-2022-1614-1683872

**US3292241**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 11 Aug 2021 22:21:07**
Was this participant screened previously?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:36:18 |
| User entered 'No (N)' | Nathan Cortez (b) (4) | 20 Aug 2020 17:17:28 |

**US3292241**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 11 Aug 2021 22:21:07**
If Yes, previous participant number

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:36:18 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 14:24:39 |



FDA-CBER-2022-1614-1683874

**US3292241**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 11 Aug 2021 22:21:07**
Enrollment Trigger

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 20 Aug 2020 17:17:36 |



FDA-CBER-2022-1614-1683875

**US3292241**
**Folder: Screening**
**Form: Inclusion/Exclusion Criteria Summary**
**Generated On: 11 Aug 2021 22:21:07**
Did the participant meet all eligibility criteria?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:36:24 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 20 Aug 2020 17:17:36 |



FDA-CBER-2022-1614-1683876

**US3292241**
**Folder: Screening**
**Form: Medical History Summary**
**Generated On: 11 Aug 2021 22:21:07**
Were any significant conditions reported?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:37:18 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:45:53 |



FDA-CBER-2022-1614-1683877

**US3292241**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:38:15 |
| 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: Sulfonamide allergy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Feb 2021 19:50:35 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Feb 2021 19:50:35 |
| Data point term sent to Coder | System | 08 Feb 2021 19:49:59 |
| DataPoint Un-verified. | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:49:02 |
| Coding entries removed. | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:49:02 |
| User entered 'Allergy to sulfa drugs' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:49:02 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:33:36 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 08 Feb 2021 16:33:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:40:49 |
| 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: Sulfonamide allergy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 21:38:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 21:38:17 |
| Data point term sent to Coder | System | 21 Aug 2020 14:47:16 |
| User entered 'Allergies - sulfa drugs' | (b) (4), (b) (6) | 21 Aug 2020 14:46:23 |



FDA-CBER-2022-1614-1683878

**US3292241**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:38:13 |
| User closed query 'Please confirm with source' (Site from CRA). | | 10 Feb 2021 19:38:10 |
| Query 'Please confirm with source' answered with 'confirmed, date matches source ' (Site from CRA). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:49:34 |
| User opened query 'Please confirm with source' (Site from CRA). | (b) (4), (b) (6) | 08 Feb 2021 16:33:31 |
| DataPoint Un-verified. | | 08 Feb 2021 16:33:16 |
| DataPoint Verified. | | 26 Jan 2021 18:40:52 |
| User entered 'un UNK 2000' | | 21 Aug 2020 14:46:23 |



FDA-CBER-2022-1614-1683879

**US3292241**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:41:04 |
| User entered '0' | | 21 Aug 2020 14:46:23 |



FDA-CBER-2022-1614-1683880

**US3292241**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:40:53 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:46:23 |



FDA-CBER-2022-1614-1683881

**US3292241**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:41:06 |
| User entered empty. | | 21 Aug 2020 14:46:23 |



FDA-CBER-2022-1614-1683882

**US3292241**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:41:07 |
| User entered '0' | | 21 Aug 2020 14:46:23 |



FDA-CBER-2022-1614-1683883

**US3292241**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 14:46:23 |

**US3292241**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 14:46:23 |



FDA-CBER-2022-1614-1683885

**US3292241**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:46:23 |



FDA-CBER-2022-1614-1683886

**US3292241**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:46:23 |



FDA-CBER-2022-1614-1683887

**US3292241**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:34:06 |
| DataPoint Un-verified. | | 08 Feb 2021 16:33:50 |
| DataPoint Verified. | | 26 Jan 2021 18:41:28 |
| 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) (b) (4) | 21 Aug 2020 14:48:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:48:25 |
| Data point term sent to Coder | System | 21 Aug 2020 14:47:19 |
| User entered 'seasonal allergies - cedar' | (b) (4), (b) (6) | 21 Aug 2020 14:46:57 |



FDA-CBER-2022-1614-1683888

**US3292241**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:34:04 |
| DataPoint Un-verified. | | 08 Feb 2021 16:33:52 |
| DataPoint Verified. | | 26 Jan 2021 18:41:29 |
| User entered 'un UNK 1959' | | 21 Aug 2020 14:46:57 |



FDA-CBER-2022-1614-1683889

**US3292241**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:41:33 |
| User entered '0' | | 21 Aug 2020 14:46:57 |



FDA-CBER-2022-1614-1683890

**US3292241**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:34:01 |
| DataPoint Un-verified. | | 08 Feb 2021 16:33:56 |
| DataPoint Verified. | | 26 Jan 2021 18:41:31 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:46:57 |



FDA-CBER-2022-1614-1683891

**US3292241**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:41:34 |
| User entered empty. | | 21 Aug 2020 14:46:57 |



FDA-CBER-2022-1614-1683892

**US3292241**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:41:36 |
| User entered '0' | | 21 Aug 2020 14:46:57 |



FDA-CBER-2022-1614-1683893

**US3292241**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 1959' | System | 21 Aug 2020 14:46:57 |



FDA-CBER-2022-1614-1683894

**US3292241**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1959' | System | 21 Aug 2020 14:46:57 |



FDA-CBER-2022-1614-1683895

**US3292241**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:46:57 |



FDA-CBER-2022-1614-1683896

**US3292241**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:46:57 |



FDA-CBER-2022-1614-1683897

**US3292241**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:34:26 |
| DataPoint Un-verified. | | 08 Feb 2021 16:34:11 |
| DataPoint Verified. | | 26 Jan 2021 18:41:42 |
| 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) (b) (4) | 27 Sep 2020 17:11:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Sep 2020 17:11:41 |
| Data point term sent to Coder | System | 21 Aug 2020 14:47:23 |
| User entered 'Seasonal allergies - oak' | (b) (4), (b) (6) | 21 Aug 2020 14:47:20 |



FDA-CBER-2022-1614-1683898

**US3292241**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:34:25 |
| DataPoint Un-verified. | | 08 Feb 2021 16:34:13 |
| DataPoint Verified. | | 26 Jan 2021 18:41:43 |
| User entered 'un UNK 1959' | | 21 Aug 2020 14:47:20 |



FDA-CBER-2022-1614-1683899

**US3292241**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:34:23 |
| DataPoint Un-verified. | | 08 Feb 2021 16:34:14 |
| DataPoint Verified. | | 26 Jan 2021 18:41:45 |
| User entered '0' | | 21 Aug 2020 14:47:20 |



FDA-CBER-2022-1614-1683900

**US3292241**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:34:21 |
| DataPoint Un-verified. | | 08 Feb 2021 16:34:15 |
| DataPoint Verified. | | 26 Jan 2021 18:41:44 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:47:20 |



FDA-CBER-2022-1614-1683901

**US3292241**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:34:19 |
| DataPoint Un-verified. | | 08 Feb 2021 16:34:17 |
| DataPoint Verified. | | 26 Jan 2021 18:41:46 |
| User entered empty. | | 21 Aug 2020 14:47:20 |



FDA-CBER-2022-1614-1683902

**US3292241**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:41:48 |
| User entered '0' | | 21 Aug 2020 14:47:20 |



FDA-CBER-2022-1614-1683903

**US3292241**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 1959' | System | 21 Aug 2020 14:47:20 |



FDA-CBER-2022-1614-1683904

**US3292241**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1959' | System | 21 Aug 2020 14:47:20 |



FDA-CBER-2022-1614-1683905

**US3292241**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:47:20 |



FDA-CBER-2022-1614-1683906

**US3292241**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:47:20 |



FDA-CBER-2022-1614-1683907

**US3292241**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:41:52 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Mycotic allergy, LLT: Allergy to molds - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 10 Sep 2020 13:53:38 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 10 Sep 2020 13:53:38 |
| Data point term sent to Coder | System | 21 Aug 2020 14:48:24 |
| User entered 'Seasonal allergies - mold' | (b) (4), (b) (6) | 21 Aug 2020 14:47:46 |



FDA-CBER-2022-1614-1683908

**US3292241**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:41:53 |
| User entered 'un UNK 1959' | | 21 Aug 2020 14:47:46 |



FDA-CBER-2022-1614-1683909

**US3292241**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:41:54 |
| User entered '0' | | 21 Aug 2020 14:47:46 |



FDA-CBER-2022-1614-1683910

**US3292241**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:41:59 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:47:46 |



FDA-CBER-2022-1614-1683911

**US3292241**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:42:00 |
| User entered empty. | | 21 Aug 2020 14:47:46 |



FDA-CBER-2022-1614-1683912

**US3292241**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:42:01 |
| User entered '0' | | 21 Aug 2020 14:47:46 |



FDA-CBER-2022-1614-1683913

**US3292241**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 1959' | System | 21 Aug 2020 14:47:46 |



FDA-CBER-2022-1614-1683914

**US3292241**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1959' | System | 21 Aug 2020 14:47:46 |



FDA-CBER-2022-1614-1683915

**US3292241**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:47:46 |



FDA-CBER-2022-1614-1683916

**US3292241**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:47:46 |



FDA-CBER-2022-1614-1683917

**US3292241**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:42:38 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 23:10:27 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 23:10:27 |
| Data point term sent to Coder | System | 21 Aug 2020 14:48:26 |
| User entered 'Food allergy - melon' | (b) (4), (b) (6) | 21 Aug 2020 14:48:11 |



FDA-CBER-2022-1614-1683918

**US3292241**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:42:40 |
| User entered 'un UNK 1960' | | 21 Aug 2020 14:48:11 |



FDA-CBER-2022-1614-1683919

**US3292241**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:42:41 |
| User entered '0' | | 21 Aug 2020 14:48:11 |



FDA-CBER-2022-1614-1683920

**US3292241**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:42:43 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:48:11 |



FDA-CBER-2022-1614-1683921

**US3292241**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:42:47 |
| User entered empty. | | 21 Aug 2020 14:48:11 |



FDA-CBER-2022-1614-1683922

**US3292241**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:42:46 |
| User entered '0' | | 21 Aug 2020 14:48:11 |



FDA-CBER-2022-1614-1683923

**US3292241**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 1960' | System | 21 Aug 2020 14:48:11 |



FDA-CBER-2022-1614-1683924

**US3292241**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1960' | System | 21 Aug 2020 14:48:11 |



FDA-CBER-2022-1614-1683925

**US3292241**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:48:11 |



FDA-CBER-2022-1614-1683926

**US3292241**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:48:11 |



FDA-CBER-2022-1614-1683927

**US3292241**
**Folder: Screening**
**Form: Medical History (6)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:42:56 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:50:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:50:18 |
| Data point term sent to Coder | System | 21 Aug 2020 14:49:30 |
| User entered 'Allergy - latex' | (b) (4), (b) (6) | 21 Aug 2020 14:48:36 |



FDA-CBER-2022-1614-1683928

**US3292241**
**Folder: Screening**
**Form: Medical History (6)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:42:57 |
| User entered 'un UNK 2000' | | 21 Aug 2020 14:48:36 |



FDA-CBER-2022-1614-1683929

**US3292241**
**Folder: Screening**
**Form: Medical History (6)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:42:58 |
| User entered '0' | | 21 Aug 2020 14:48:36 |



FDA-CBER-2022-1614-1683930

**US3292241**
**Folder: Screening**
**Form: Medical History (6)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:43:00 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:48:36 |



FDA-CBER-2022-1614-1683931

**US3292241**
**Folder: Screening**
**Form: Medical History (6)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:43:01 |
| User entered empty. | | 21 Aug 2020 14:48:36 |



FDA-CBER-2022-1614-1683932

**US3292241**
**Folder: Screening**
**Form: Medical History (6)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:43:02 |
| User entered '0' | | 21 Aug 2020 14:48:36 |



FDA-CBER-2022-1614-1683933

**US3292241**
**Folder: Screening**
**Form: Medical History (6)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 14:48:36 |

**US3292241**
**Folder: Screening**
**Form: Medical History (6)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 14:48:36 |



FDA-CBER-2022-1614-1683935

**US3292241**
**Folder: Screening**
**Form: Medical History (6)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:48:36 |



FDA-CBER-2022-1614-1683936

**US3292241**
**Folder: Screening**
**Form: Medical History (6)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:48:36 |



FDA-CBER-2022-1614-1683937

**US3292241**
**Folder: Screening**
**Form: Medical History (7)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:49:40 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Hormonal therapeutic procedures NEC, PT: Hormone replacement therapy, LLT: Hormone replacement therapy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:50:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:50:17 |
| Data point term sent to Coder | System | 21 Aug 2020 14:49:30 |
| User entered 'Hormone replacement therapy' | (b) (4), (b) (6) | 21 Aug 2020 14:49:17 |



FDA-CBER-2022-1614-1683938

**US3292241**
**Folder: Screening**
**Form: Medical History (7)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:49:41 |
| User entered 'un UNK 2000' | | 21 Aug 2020 14:49:17 |



FDA-CBER-2022-1614-1683939

**US3292241**
**Folder: Screening**
**Form: Medical History (7)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:49:44 |
| User entered '0' | | 21 Aug 2020 14:49:17 |



FDA-CBER-2022-1614-1683940

**US3292241**
**Folder: Screening**
**Form: Medical History (7)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:49:42 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:49:17 |



FDA-CBER-2022-1614-1683941

**US3292241**
**Folder: Screening**
**Form: Medical History (7)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:49:46 |
| User entered empty. | | 21 Aug 2020 14:49:17 |



FDA-CBER-2022-1614-1683942

**US3292241**
**Folder: Screening**
**Form: Medical History (7)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:49:47 |
| User entered '0' | | 21 Aug 2020 14:49:17 |



FDA-CBER-2022-1614-1683943

**US3292241**
**Folder: Screening**
**Form: Medical History (7)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 14:49:17 |

**US3292241**
**Folder: Screening**
**Form: Medical History (7)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 14:49:17 |



FDA-CBER-2022-1614-1683945

**US3292241**
**Folder: Screening**
**Form: Medical History (7)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:49:17 |



FDA-CBER-2022-1614-1683946

**US3292241**
**Folder: Screening**
**Form: Medical History (7)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:49:17 |



FDA-CBER-2022-1614-1683947

**US3292241**
**Folder: Screening**
**Form: Medical History (8)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:49:54 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:51:21 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:51:21 |
| Data point term sent to Coder | System | 21 Aug 2020 14:50:35 |
| User entered 'Cholecystectomy' | (b) (4), (b) (6) | 21 Aug 2020 14:49:47 |



FDA-CBER-2022-1614-1683948

**US3292241**
**Folder: Screening**
**Form: Medical History (8)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:49:56 |
| User entered 'un UNK 2003' | | 21 Aug 2020 14:49:47 |



FDA-CBER-2022-1614-1683949

**US3292241**
**Folder: Screening**
**Form: Medical History (8)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:50:03 |
| User entered '0' | | 21 Aug 2020 14:49:47 |



FDA-CBER-2022-1614-1683950

**US3292241**
**Folder: Screening**
**Form: Medical History (8)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:49:57 |
| User entered 'No (N)' | | 21 Aug 2020 14:49:47 |



FDA-CBER-2022-1614-1683951

**US3292241**
**Folder: Screening**
**Form: Medical History (8)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:50:01 |
| User entered 'un UNK 2003' | | 21 Aug 2020 14:49:47 |



FDA-CBER-2022-1614-1683952

**US3292241**
**Folder: Screening**
**Form: Medical History (8)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:50:21 |
| User entered '0' | | 21 Aug 2020 14:49:47 |



FDA-CBER-2022-1614-1683953

**US3292241**
**Folder: Screening**
**Form: Medical History (8)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2003' | System | 21 Aug 2020 14:49:47 |



FDA-CBER-2022-1614-1683954

**US3292241**
**Folder: Screening**
**Form: Medical History (8)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2003' | System | 21 Aug 2020 14:49:47 |



FDA-CBER-2022-1614-1683955

**US3292241**
**Folder: Screening**
**Form: Medical History (8)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2003' | System | 21 Aug 2020 14:49:47 |



FDA-CBER-2022-1614-1683956

**US3292241**
**Folder: Screening**
**Form: Medical History (8)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2003' | System | 21 Aug 2020 14:49:47 |



FDA-CBER-2022-1614-1683957

**US3292241**
**Folder: Screening**
**Form: Medical History (9)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:50:43 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:51:21 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:51:21 |
| Data point term sent to Coder | System | 21 Aug 2020 14:50:35 |
| User entered 'Thyroidectomy' | (b) (4), (b) (6) | 21 Aug 2020 14:50:12 |



FDA-CBER-2022-1614-1683958

**US3292241**
**Folder: Screening**
**Form: Medical History (9)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:50:45 |
| User entered 'un UNK 2001' | | 21 Aug 2020 14:50:12 |



FDA-CBER-2022-1614-1683959

**US3292241**
**Folder: Screening**
**Form: Medical History (9)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:50:46 |
| User entered '0' | | 21 Aug 2020 14:50:12 |



FDA-CBER-2022-1614-1683960

**US3292241**
**Folder: Screening**
**Form: Medical History (9)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:50:49 |
| User entered 'No (N)' | | 21 Aug 2020 14:50:12 |



FDA-CBER-2022-1614-1683961

**US3292241**
**Folder: Screening**
**Form: Medical History (9)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:50:50 |
| User entered 'un UNK 2001' | | 21 Aug 2020 14:50:12 |



FDA-CBER-2022-1614-1683962

**US3292241**
**Folder: Screening**
**Form: Medical History (9)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:50:52 |
| User entered '0' | | 21 Aug 2020 14:50:12 |



FDA-CBER-2022-1614-1683963

**US3292241**
**Folder: Screening**
**Form: Medical History (9)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2001' | System | 21 Aug 2020 14:50:12 |

**US3292241**
**Folder: Screening**
**Form: Medical History (9)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2001' | System | 21 Aug 2020 14:50:12 |



FDA-CBER-2022-1614-1683965

**US3292241**
**Folder: Screening**
**Form: Medical History (9)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2001' | System | 21 Aug 2020 14:50:12 |



FDA-CBER-2022-1614-1683966

**US3292241**
**Folder: Screening**
**Form: Medical History (9)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2001' | System | 21 Aug 2020 14:50:12 |



FDA-CBER-2022-1614-1683967

**US3292241**
**Folder: Screening**
**Form: Medical History (10)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:52:40 |
| User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Delivery, LLT: Vaginal delivery - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:51:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:51:38 |
| Data point term sent to Coder | System | 21 Aug 2020 14:50:35 |
| User entered 'Vaginal delivery' | (b) (4), (b) (6) | 21 Aug 2020 14:50:32 |



FDA-CBER-2022-1614-1683968

**US3292241**
**Folder: Screening**
**Form: Medical History (10)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:52:42 |
| User entered 'un UNK 1989' | | 21 Aug 2020 14:50:32 |



FDA-CBER-2022-1614-1683969

**US3292241**
**Folder: Screening**
**Form: Medical History (10)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:52:43 |
| User entered '0' | | 21 Aug 2020 14:50:32 |



FDA-CBER-2022-1614-1683970

**US3292241**
**Folder: Screening**
**Form: Medical History (10)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:52:45 |
| User entered 'No (N)' | | 21 Aug 2020 14:50:32 |



FDA-CBER-2022-1614-1683971

**US3292241**
**Folder: Screening**
**Form: Medical History (10)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:52:46 |
| User entered 'un UNK 1989' | | 21 Aug 2020 14:50:32 |



FDA-CBER-2022-1614-1683972

**US3292241**
**Folder: Screening**
**Form: Medical History (10)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:52:47 |
| User entered '0' | | 21 Aug 2020 14:50:32 |



FDA-CBER-2022-1614-1683973

**US3292241**
**Folder: Screening**
**Form: Medical History (10)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 1989' | System | 21 Aug 2020 14:50:32 |

**US3292241**
**Folder: Screening**
**Form: Medical History (10)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1989' | System | 21 Aug 2020 14:50:32 |



FDA-CBER-2022-1614-1683975

**US3292241**
**Folder: Screening**
**Form: Medical History (10)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 1989' | System | 21 Aug 2020 14:50:32 |



FDA-CBER-2022-1614-1683976

**US3292241**
**Folder: Screening**
**Form: Medical History (10)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1989' | System | 21 Aug 2020 14:50:32 |



FDA-CBER-2022-1614-1683977

**US3292241**
**Folder: Screening**
**Form: Medical History (11)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:52:56 |
| User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Delivery, LLT: Vaginal delivery - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:52:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:52:25 |
| Data point term sent to Coder | System | 21 Aug 2020 14:51:38 |
| User entered 'Vaginal delivery' | (b) (4), (b) (6) | 21 Aug 2020 14:50:57 |



FDA-CBER-2022-1614-1683978

**US3292241**
**Folder: Screening**
**Form: Medical History (11)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:52:58 |
| User entered 'un UNK 1991' | | 21 Aug 2020 14:50:57 |



FDA-CBER-2022-1614-1683979

**US3292241**
**Folder: Screening**
**Form: Medical History (11)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:53:02 |
| User entered '0' | | 21 Aug 2020 14:50:57 |



FDA-CBER-2022-1614-1683980

**US3292241**
**Folder: Screening**
**Form: Medical History (11)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:53:00 |
| User entered 'No (N)' | | 21 Aug 2020 14:50:57 |



FDA-CBER-2022-1614-1683981

**US3292241**
**Folder: Screening**
**Form: Medical History (11)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:53:04 |
| User entered 'un UNK 1991' | | 21 Aug 2020 14:50:57 |



FDA-CBER-2022-1614-1683982

**US3292241**
**Folder: Screening**
**Form: Medical History (11)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:53:06 |
| User entered '0' | | 21 Aug 2020 14:50:57 |



FDA-CBER-2022-1614-1683983

**US3292241**
**Folder: Screening**
**Form: Medical History (11)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 1991' | System | 21 Aug 2020 14:50:57 |



FDA-CBER-2022-1614-1683984

**US3292241**
**Folder: Screening**
**Form: Medical History (11)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1991' | System | 21 Aug 2020 14:50:57 |



FDA-CBER-2022-1614-1683985

**US3292241**
**Folder: Screening**
**Form: Medical History (11)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 1991' | System | 21 Aug 2020 14:50:57 |



FDA-CBER-2022-1614-1683986

**US3292241**
**Folder: Screening**
**Form: Medical History (11)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1991' | System | 21 Aug 2020 14:50:57 |



FDA-CBER-2022-1614-1683987

**US3292241**
**Folder: Screening**
**Form: Medical History (12)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:53:20 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Cervical discectomy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 23:05:23 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 23:05:23 |
| Data point term sent to Coder | System | 21 Aug 2020 14:52:40 |
| User entered 'Discectomy - C5-C6' | (b) (4), (b) (6) | 21 Aug 2020 14:51:53 |



FDA-CBER-2022-1614-1683988

**US3292241**
**Folder: Screening**
**Form: Medical History (12)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:53:22 |
| User entered 'un UNK 2007' | | 21 Aug 2020 14:51:53 |



FDA-CBER-2022-1614-1683989

**US3292241**
**Folder: Screening**
**Form: Medical History (12)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:53:23 |
| User entered '0' | | 21 Aug 2020 14:51:53 |



FDA-CBER-2022-1614-1683990

**US3292241**
**Folder: Screening**
**Form: Medical History (12)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:53:27 |
| User entered 'No (N)' | | 21 Aug 2020 14:51:53 |



FDA-CBER-2022-1614-1683991

**US3292241**
**Folder: Screening**
**Form: Medical History (12)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:53:29 |
| User entered 'un UNK 2007' | | 21 Aug 2020 14:51:53 |



FDA-CBER-2022-1614-1683992

**US3292241**
**Folder: Screening**
**Form: Medical History (12)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:53:31 |
| User entered '0' | | 21 Aug 2020 14:51:53 |



FDA-CBER-2022-1614-1683993

**US3292241**
**Folder: Screening**
**Form: Medical History (12)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2007' | System | 21 Aug 2020 14:51:53 |



FDA-CBER-2022-1614-1683994

**US3292241**
**Folder: Screening**
**Form: Medical History (12)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2007' | System | 21 Aug 2020 14:51:53 |



FDA-CBER-2022-1614-1683995

**US3292241**
**Folder: Screening**
**Form: Medical History (12)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2007' | System | 21 Aug 2020 14:51:53 |



FDA-CBER-2022-1614-1683996

**US3292241**
**Folder: Screening**
**Form: Medical History (12)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2007' | System | 21 Aug 2020 14:51:53 |



FDA-CBER-2022-1614-1683997

**US3292241**
**Folder: Screening**
**Form: Medical History (13)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:54:08 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:53:26 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:53:26 |
| Data point term sent to Coder | System | 21 Aug 2020 14:52:43 |
| User entered 'Total hysterectomy' | (b) (4), (b) (6) | 21 Aug 2020 14:52:25 |



FDA-CBER-2022-1614-1683998

**US3292241**
**Folder: Screening**
**Form: Medical History (13)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:54:10 |
| User entered 'un UNK 2000' | | 21 Aug 2020 14:52:25 |



FDA-CBER-2022-1614-1683999

**US3292241**
**Folder: Screening**
**Form: Medical History (13)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:54:12 |
| User entered '0' | | 21 Aug 2020 14:52:25 |



FDA-CBER-2022-1614-1684000

**US3292241**
**Folder: Screening**
**Form: Medical History (13)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:54:15 |
| User entered 'No (N)' | | 21 Aug 2020 14:52:25 |



FDA-CBER-2022-1614-1684001

**US3292241**
**Folder: Screening**
**Form: Medical History (13)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:54:23 |
| User entered 'un UNK 2000' | | 21 Aug 2020 14:52:25 |



FDA-CBER-2022-1614-1684002

**US3292241**
**Folder: Screening**
**Form: Medical History (13)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:54:25 |
| User entered '0' | | 21 Aug 2020 14:52:25 |



FDA-CBER-2022-1614-1684003

**US3292241**
**Folder: Screening**
**Form: Medical History (13)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 14:52:25 |

**US3292241**
**Folder: Screening**
**Form: Medical History (13)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 14:52:25 |



FDA-CBER-2022-1614-1684005

**US3292241**
**Folder: Screening**
**Form: Medical History (13)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 14:52:25 |



FDA-CBER-2022-1614-1684006

**US3292241**
**Folder: Screening**
**Form: Medical History (13)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 14:52:25 |



FDA-CBER-2022-1614-1684007

**US3292241**
**Folder: Screening**
**Form: Medical History (14)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:13 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Fallopian tube therapeutic procedures, PT: Salpingo-oophorectomy bilateral, LLT: Bilateral salpingo-oophorectomy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 21:58:27 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 21:58:27 |
| Data point term sent to Coder | System | 21 Aug 2020 14:54:48 |
| User entered 'Bilateral salpingo - oophorectomy' | (b) (4), (b) (6) | 21 Aug 2020 14:54:19 |



FDA-CBER-2022-1614-1684008

**US3292241**
**Folder: Screening**
**Form: Medical History (14)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:14 |
| User entered 'un UNK 2000' | | 21 Aug 2020 14:54:19 |



FDA-CBER-2022-1614-1684009

**US3292241**
**Folder: Screening**
**Form: Medical History (14)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:16 |
| User entered '0' | | 21 Aug 2020 14:54:19 |



FDA-CBER-2022-1614-1684010

**US3292241**
**Folder: Screening**
**Form: Medical History (14)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:17 |
| User entered 'No (N)' | | 21 Aug 2020 14:54:19 |



FDA-CBER-2022-1614-1684011

**US3292241**
**Folder: Screening**
**Form: Medical History (14)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:19 |
| User entered 'un UNK 2000' | | 21 Aug 2020 14:54:19 |



FDA-CBER-2022-1614-1684012

**US3292241**
**Folder: Screening**
**Form: Medical History (14)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:20 |
| User entered '0' | | 21 Aug 2020 14:54:19 |



FDA-CBER-2022-1614-1684013

**US3292241**
**Folder: Screening**
**Form: Medical History (14)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 14:54:19 |

**US3292241**
**Folder: Screening**
**Form: Medical History (14)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 14:54:19 |



FDA-CBER-2022-1614-1684015

**US3292241**
**Folder: Screening**
**Form: Medical History (14)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 14:54:19 |



FDA-CBER-2022-1614-1684016

**US3292241**
**Folder: Screening**
**Form: Medical History (14)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 14:54:19 |



FDA-CBER-2022-1614-1684017

**US3292241**
**Folder: Screening**
**Form: Medical History (15)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:33 |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:55:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:55:18 |
| Data point term sent to Coder | System | 21 Aug 2020 14:54:48 |
| User entered 'Myopia' | (b) (4), (b) (6) | 21 Aug 2020 14:54:38 |



FDA-CBER-2022-1614-1684018

**US3292241**
**Folder: Screening**
**Form: Medical History (15)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:34 |
| User entered 'un UNK 1967' | | 21 Aug 2020 14:54:38 |



FDA-CBER-2022-1614-1684019

**US3292241**
**Folder: Screening**
**Form: Medical History (15)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:36 |
| User entered '0' | | 21 Aug 2020 14:54:38 |



FDA-CBER-2022-1614-1684020

**US3292241**
**Folder: Screening**
**Form: Medical History (15)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:37 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:54:38 |



FDA-CBER-2022-1614-1684021

**US3292241**
**Folder: Screening**
**Form: Medical History (15)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:38 |
| User entered empty. | | 21 Aug 2020 14:54:38 |



FDA-CBER-2022-1614-1684022

**US3292241**
**Folder: Screening**
**Form: Medical History (15)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:40 |
| User entered '0' | | 21 Aug 2020 14:54:38 |



FDA-CBER-2022-1614-1684023

**US3292241**
**Folder: Screening**
**Form: Medical History (15)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 1967' | System | 21 Aug 2020 14:54:38 |



FDA-CBER-2022-1614-1684024

**US3292241**
**Folder: Screening**
**Form: Medical History (15)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1967' | System | 21 Aug 2020 14:54:38 |



FDA-CBER-2022-1614-1684025

**US3292241**
**Folder: Screening**
**Form: Medical History (15)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:54:38 |



FDA-CBER-2022-1614-1684026

**US3292241**
**Folder: Screening**
**Form: Medical History (15)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:54:38 |



FDA-CBER-2022-1614-1684027

**US3292241**
**Folder: Screening**
**Form: Medical History (16)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:56 |
| User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eyes - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:57:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:57:17 |
| Data point term sent to Coder | System | 21 Aug 2020 14:55:51 |
| User entered 'Dry eyes' | (b) (4), (b) (6) | 21 Aug 2020 14:54:57 |



FDA-CBER-2022-1614-1684028

**US3292241**
**Folder: Screening**
**Form: Medical History (16)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:57 |
| User entered 'un UNK 2000' | | 21 Aug 2020 14:54:57 |



FDA-CBER-2022-1614-1684029

**US3292241**
**Folder: Screening**
**Form: Medical History (16)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:55:59 |
| User entered '0' | | 21 Aug 2020 14:54:57 |



FDA-CBER-2022-1614-1684030

**US3292241**
**Folder: Screening**
**Form: Medical History (16)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:56:08 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:54:57 |



FDA-CBER-2022-1614-1684031

**US3292241**
**Folder: Screening**
**Form: Medical History (16)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:56:10 |
| User entered empty. | | 21 Aug 2020 14:54:57 |



FDA-CBER-2022-1614-1684032

**US3292241**
**Folder: Screening**
**Form: Medical History (16)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:56:12 |
| User entered '0' | | 21 Aug 2020 14:54:57 |

**US3292241**
**Folder: Screening**
**Form: Medical History (16)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 14:54:57 |

**US3292241**
**Folder: Screening**
**Form: Medical History (16)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 14:54:57 |



FDA-CBER-2022-1614-1684035

**US3292241**
**Folder: Screening**
**Form: Medical History (16)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:54:57 |

**US3292241**
**Folder: Screening**
**Form: Medical History (16)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:54:57 |



FDA-CBER-2022-1614-1684037

**US3292241**
**Folder: Screening**
**Form: Medical History (17)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:56:35 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:57:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:57:17 |
| Data point term sent to Coder | System | 21 Aug 2020 14:55:53 |
| User entered 'Asthma' | (b) (4), (b) (6) | 21 Aug 2020 14:55:34 |



FDA-CBER-2022-1614-1684038

**US3292241**
**Folder: Screening**
**Form: Medical History (17)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:56:37 |
| User entered 'un UNK 1983' | | 21 Aug 2020 14:55:34 |



FDA-CBER-2022-1614-1684039

**US3292241**
**Folder: Screening**
**Form: Medical History (17)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:56:39 |
| User entered '0' | | 21 Aug 2020 14:55:34 |



FDA-CBER-2022-1614-1684040

**US3292241**
**Folder: Screening**
**Form: Medical History (17)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:56:41 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:55:34 |



FDA-CBER-2022-1614-1684041

**US3292241**
**Folder: Screening**
**Form: Medical History (17)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:56:42 |
| User entered empty. | | 21 Aug 2020 14:55:34 |



FDA-CBER-2022-1614-1684042

**US3292241**
**Folder: Screening**
**Form: Medical History (17)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:56:43 |
| User entered '0' | | 21 Aug 2020 14:55:34 |



FDA-CBER-2022-1614-1684043

**US3292241**
**Folder: Screening**
**Form: Medical History (17)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 1983' | System | 21 Aug 2020 14:55:34 |



FDA-CBER-2022-1614-1684044

**US3292241**
**Folder: Screening**
**Form: Medical History (17)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1983' | System | 21 Aug 2020 14:55:34 |



FDA-CBER-2022-1614-1684045

**US3292241**
**Folder: Screening**
**Form: Medical History (17)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:55:34 |



FDA-CBER-2022-1614-1684046

**US3292241**
**Folder: Screening**
**Form: Medical History (17)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:55:34 |



FDA-CBER-2022-1614-1684047

**US3292241**
**Folder: Screening**
**Form: Medical History (18)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:11 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:57:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:57:17 |
| Data point term sent to Coder | System | 21 Aug 2020 14:55:53 |
| User entered 'Hypertension' | (b) (4), (b) (6) | 21 Aug 2020 14:55:49 |



FDA-CBER-2022-1614-1684048

**US3292241**
**Folder: Screening**
**Form: Medical History (18)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:12 |
| User entered 'un UNK 2000' | | 21 Aug 2020 14:55:49 |



FDA-CBER-2022-1614-1684049

**US3292241**
**Folder: Screening**
**Form: Medical History (18)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:14 |
| User entered '0' | | 21 Aug 2020 14:55:49 |



FDA-CBER-2022-1614-1684050

**US3292241**
**Folder: Screening**
**Form: Medical History (18)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:15 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:55:49 |



FDA-CBER-2022-1614-1684051

**US3292241**
**Folder: Screening**
**Form: Medical History (18)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:17 |
| User entered empty. | | 21 Aug 2020 14:55:49 |



FDA-CBER-2022-1614-1684052

**US3292241**
**Folder: Screening**
**Form: Medical History (18)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:18 |
| User entered '0' | | 21 Aug 2020 14:55:49 |



FDA-CBER-2022-1614-1684053

**US3292241**
**Folder: Screening**
**Form: Medical History (18)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 14:55:49 |

**US3292241**
**Folder: Screening**
**Form: Medical History (18)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 14:55:49 |



FDA-CBER-2022-1614-1684055

**US3292241**
**Folder: Screening**
**Form: Medical History (18)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:55:49 |



FDA-CBER-2022-1614-1684056

**US3292241**
**Folder: Screening**
**Form: Medical History (18)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:55:49 |

**US3292241**
**Folder: Screening**
**Form: Medical History (19)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:28 |
| 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) (b) (4) | 21 Aug 2020 14:57:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:57:18 |
| Data point term sent to Coder | System | 21 Aug 2020 14:56:55 |
| User entered 'Constipation' | (b) (4), (b) (6) | 21 Aug 2020 14:56:07 |



FDA-CBER-2022-1614-1684058

**US3292241**
**Folder: Screening**
**Form: Medical History (19)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:30 |
| User entered 'un UNK 2000' | | 21 Aug 2020 14:56:07 |



FDA-CBER-2022-1614-1684059

**US3292241**
**Folder: Screening**
**Form: Medical History (19)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:34 |
| User entered '0' | | 21 Aug 2020 14:56:07 |



FDA-CBER-2022-1614-1684060

**US3292241**
**Folder: Screening**
**Form: Medical History (19)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:32 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:56:07 |



FDA-CBER-2022-1614-1684061

**US3292241**
**Folder: Screening**
**Form: Medical History (19)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:35 |
| User entered empty. | | 21 Aug 2020 14:56:07 |



FDA-CBER-2022-1614-1684062

**US3292241**
**Folder: Screening**
**Form: Medical History (19)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:37 |
| User entered '0' | | 21 Aug 2020 14:56:07 |



FDA-CBER-2022-1614-1684063

**US3292241**
**Folder: Screening**
**Form: Medical History (19)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 14:56:07 |

**US3292241**
**Folder: Screening**
**Form: Medical History (19)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 14:56:07 |



FDA-CBER-2022-1614-1684065

**US3292241**
**Folder: Screening**
**Form: Medical History (19)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:56:07 |

**US3292241**
**Folder: Screening**
**Form: Medical History (19)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:56:07 |

**US3292241**
**Folder: Screening**
**Form: Medical History (20)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:49 |
| User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:57:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:57:18 |
| Data point term sent to Coder | System | 21 Aug 2020 14:56:56 |
| User entered 'Cholelithiasis' | (b) (4), (b) (6) | 21 Aug 2020 14:56:47 |



FDA-CBER-2022-1614-1684068

**US3292241**
**Folder: Screening**
**Form: Medical History (20)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:50 |
| User entered 'un UNK 2003' | | 21 Aug 2020 14:56:47 |



FDA-CBER-2022-1614-1684069

**US3292241**
**Folder: Screening**
**Form: Medical History (20)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:52 |
| User entered '0' | | 21 Aug 2020 14:56:47 |



FDA-CBER-2022-1614-1684070

**US3292241**
**Folder: Screening**
**Form: Medical History (20)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:53 |
| User entered 'No (N)' | | 21 Aug 2020 14:56:47 |



FDA-CBER-2022-1614-1684071

**US3292241**
**Folder: Screening**
**Form: Medical History (20)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:55 |
| User entered 'un UNK 2003' | | 21 Aug 2020 14:56:47 |



FDA-CBER-2022-1614-1684072

**US3292241**
**Folder: Screening**
**Form: Medical History (20)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:57:57 |
| User entered '0' | | 21 Aug 2020 14:56:47 |



FDA-CBER-2022-1614-1684073

**US3292241**
**Folder: Screening**
**Form: Medical History (20)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2003' | System | 21 Aug 2020 14:56:47 |

**US3292241**
**Folder: Screening**
**Form: Medical History (20)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2003' | System | 21 Aug 2020 14:56:47 |



FDA-CBER-2022-1614-1684075

**US3292241**
**Folder: Screening**
**Form: Medical History (20)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2003' | System | 21 Aug 2020 14:56:47 |



FDA-CBER-2022-1614-1684076

**US3292241**
**Folder: Screening**
**Form: Medical History (20)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2003' | System | 21 Aug 2020 14:56:47 |



FDA-CBER-2022-1614-1684077

**US3292241**
**Folder: Screening**
**Form: Medical History (21)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:58:28 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM). | | 30 Nov 2020 16:02:26 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'incorrect. Nature thyroid entered in EDC for indication hypothyroidism' (Site from DM). | | 21 Sep 2020 19:47:31 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM). | | 21 Sep 2020 13:11:29 |
| User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:59:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:59:24 |
| Data point term sent to Coder | System | 21 Aug 2020 14:57:57 |
| User entered 'Hypothyroidism' | (b) (4), (b) (6) | 21 Aug 2020 14:57:12 |



FDA-CBER-2022-1614-1684078

**US3292241**
**Folder: Screening**
**Form: Medical History (21)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:58:29 |
| User entered 'un UNK 2001' | | 21 Aug 2020 14:57:12 |



FDA-CBER-2022-1614-1684079

**US3292241**
**Folder: Screening**
**Form: Medical History (21)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:58:34 |
| User entered '0' | | 21 Aug 2020 14:57:12 |



FDA-CBER-2022-1614-1684080

**US3292241**
**Folder: Screening**
**Form: Medical History (21)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:58:31 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | | 21 Aug 2020 14:57:36 |
| User entered 'No (N)' | | 21 Aug 2020 14:57:12 |



FDA-CBER-2022-1614-1684081

**US3292241**
**Folder: Screening**
**Form: Medical History (21)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:58:32 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Aug 2020 14:57:51 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 21 Aug 2020 14:57:51 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Aug 2020 14:57:36 |
| User entered 'N UNK 2001' (non-conformant). | (b) (4), (b) (6) | 21 Aug 2020 14:57:36 |
| User entered 'un UNK 2001' | | 21 Aug 2020 14:57:12 |

**US3292241**
**Folder: Screening**
**Form: Medical History (21)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:58:35 |
| User entered '0' | | 21 Aug 2020 14:57:12 |



FDA-CBER-2022-1614-1684083

**US3292241**
**Folder: Screening**
**Form: Medical History (21)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2001' | System | 21 Aug 2020 14:57:12 |

**US3292241**
**Folder: Screening**
**Form: Medical History (21)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2001' | System | 21 Aug 2020 14:57:12 |



FDA-CBER-2022-1614-1684085

**US3292241**
**Folder: Screening**
**Form: Medical History (21)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:57:36 |
| User entered 'Jan 2001' | System | 21 Aug 2020 14:57:12 |



FDA-CBER-2022-1614-1684086

**US3292241**
**Folder: Screening**
**Form: Medical History (21)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:57:36 |
| User entered '2001' | System | 21 Aug 2020 14:57:12 |

**US3292241**
**Folder: Screening**
**Form: Medical History (22)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:58:55 |
| User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Hyperthyroidism, LLT: Hyperthyroidism - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:59:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 14:59:25 |
| Data point term sent to Coder | System | 21 Aug 2020 14:59:02 |
| User entered 'Hyperthyroidism' | (b) (4), (b) (6) | 21 Aug 2020 14:58:18 |



FDA-CBER-2022-1614-1684088

**US3292241**
**Folder: Screening**
**Form: Medical History (22)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:58:58 |
| User entered 'un UNK 2001' | | 21 Aug 2020 14:58:18 |



FDA-CBER-2022-1614-1684089

**US3292241**
**Folder: Screening**
**Form: Medical History (22)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:00 |
| User entered '0' | | 21 Aug 2020 14:58:18 |



FDA-CBER-2022-1614-1684090

**US3292241**
**Folder: Screening**
**Form: Medical History (22)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:02 |
| User entered 'No (N)' | | 21 Aug 2020 14:58:18 |



FDA-CBER-2022-1614-1684091

**US3292241**
**Folder: Screening**
**Form: Medical History (22)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:03 |
| User entered 'un UNK 2001' | | 21 Aug 2020 14:58:18 |



FDA-CBER-2022-1614-1684092

**US3292241**
**Folder: Screening**
**Form: Medical History (22)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:04 |
| User entered '0' | | 21 Aug 2020 14:58:18 |



FDA-CBER-2022-1614-1684093

**US3292241**
**Folder: Screening**
**Form: Medical History (22)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2001' | System | 21 Aug 2020 14:58:18 |

**US3292241**
**Folder: Screening**
**Form: Medical History (22)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2001' | System | 21 Aug 2020 14:58:18 |



FDA-CBER-2022-1614-1684095

**US3292241**
**Folder: Screening**
**Form: Medical History (22)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2001' | System | 21 Aug 2020 14:58:18 |



FDA-CBER-2022-1614-1684096

**US3292241**
**Folder: Screening**
**Form: Medical History (22)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2001' | System | 21 Aug 2020 14:58:18 |



FDA-CBER-2022-1614-1684097

**US3292241**
**Folder: Screening**
**Form: Medical History (23)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:10 |
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menopause related conditions, HLT: Menopausal effects NEC, PT: Artificial menopause, LLT: Surgical menopause - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:00:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:00:25 |
| Data point term sent to Coder | System | 21 Aug 2020 14:59:05 |
| User entered 'Surgical menopause' | (b) (4), (b) (6) | 21 Aug 2020 14:59:03 |



FDA-CBER-2022-1614-1684098

**US3292241**
**Folder: Screening**
**Form: Medical History (23)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:11 |
| User entered 'un UNK 2000' | | 21 Aug 2020 14:59:03 |



FDA-CBER-2022-1614-1684099

**US3292241**
**Folder: Screening**
**Form: Medical History (23)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:21 |
| User entered '0' | | 21 Aug 2020 14:59:03 |



FDA-CBER-2022-1614-1684100

**US3292241**
**Folder: Screening**
**Form: Medical History (23)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:23 |
| User entered 'Yes (Y)' | | 21 Aug 2020 14:59:03 |



FDA-CBER-2022-1614-1684101

**US3292241**
**Folder: Screening**
**Form: Medical History (23)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:24 |
| User entered empty. | | 21 Aug 2020 14:59:03 |

**US3292241**
**Folder: Screening**
**Form: Medical History (23)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:26 |
| User entered '0' | | 21 Aug 2020 14:59:03 |



FDA-CBER-2022-1614-1684103

**US3292241**
**Folder: Screening**
**Form: Medical History (23)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 14:59:03 |

**US3292241**
**Folder: Screening**
**Form: Medical History (23)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 14:59:03 |



FDA-CBER-2022-1614-1684105

**US3292241**
**Folder: Screening**
**Form: Medical History (23)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:59:03 |



FDA-CBER-2022-1614-1684106

**US3292241**
**Folder: Screening**
**Form: Medical History (23)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 14:59:03 |



FDA-CBER-2022-1614-1684107

**US3292241**
**Folder: Screening**
**Form: Medical History (24)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:38 |
| User closed query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of MH #12 DISCECTOMY was performed in UN UNK 2007. Please review and update if appropriate. Otherwise, clarify.' (Site from DM). | | 30 Nov 2020 16:02:54 |
| Query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of MH #12 DISCECTOMY was performed in UN UNK 2007. Please review and update if appropriate. Otherwise, clarify.' answered with 'updated ' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:54:30 |
| User opened query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of MH #12 DISCECTOMY was performed in UN UNK 2007. Please review and update if appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 21 Sep 2020 13:12:01 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Intervertebral disc bulging - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 25 Aug 2020 21:18:39 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 25 Aug 2020 21:18:39 |
| Data point term sent to Coder | System | 21 Aug 2020 15:00:08 |
| User entered 'Bulging disc (C5,C6)' | (b) (4), (b) (6) | 21 Aug 2020 14:59:41 |

**US3292241**
**Folder: Screening**
**Form: Medical History (24)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:39 |
| User entered 'un UNK 2007' | | 21 Aug 2020 14:59:41 |



FDA-CBER-2022-1614-1684109

**US3292241**
**Folder: Screening**
**Form: Medical History (24)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:42 |
| User entered '0' | | 21 Aug 2020 14:59:41 |



FDA-CBER-2022-1614-1684110

**US3292241**
**Folder: Screening**
**Form: Medical History (24)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:43 |
| User entered 'No (N)' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:54:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 14:59:41 |



FDA-CBER-2022-1614-1684111

**US3292241**
**Folder: Screening**
**Form: Medical History (24)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:44 |
| User entered 'UN UNK 2007' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:54:16 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 14:59:41 |



FDA-CBER-2022-1614-1684112

**US3292241**
**Folder: Screening**
**Form: Medical History (24)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:46 |
| User entered '0' | | 21 Aug 2020 14:59:41 |



FDA-CBER-2022-1614-1684113

**US3292241**
**Folder: Screening**
**Form: Medical History (24)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2007' | System | 21 Aug 2020 14:59:41 |



FDA-CBER-2022-1614-1684114

**US3292241**
**Folder: Screening**
**Form: Medical History (24)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2007' | System | 21 Aug 2020 14:59:41 |



FDA-CBER-2022-1614-1684115

**US3292241**
**Folder: Screening**
**Form: Medical History (24)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2007' | System | 21 Sep 2020 23:54:16 |
| User entered empty. | System | 21 Aug 2020 14:59:41 |



FDA-CBER-2022-1614-1684116

**US3292241**
**Folder: Screening**
**Form: Medical History (24)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2007' | System | 21 Sep 2020 23:54:16 |
| User entered empty. | System | 21 Aug 2020 14:59:41 |



FDA-CBER-2022-1614-1684117

**US3292241**
**Folder: Screening**
**Form: Medical History (25)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:54 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:02:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:02:17 |
| Data point term sent to Coder | System | 21 Aug 2020 15:01:11 |
| User entered 'Insomnia' | (b) (4), (b) (6) | 21 Aug 2020 15:00:38 |



FDA-CBER-2022-1614-1684118

**US3292241**
**Folder: Screening**
**Form: Medical History (25)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:55 |
| User entered 'un UNK 2015' | | 21 Aug 2020 15:00:38 |



FDA-CBER-2022-1614-1684119

**US3292241**
**Folder: Screening**
**Form: Medical History (25)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:56 |
| User entered '0' | | 21 Aug 2020 15:00:38 |



FDA-CBER-2022-1614-1684120

**US3292241**
**Folder: Screening**
**Form: Medical History (25)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:58 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:00:38 |



FDA-CBER-2022-1614-1684121

**US3292241**
**Folder: Screening**
**Form: Medical History (25)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 18:59:59 |
| User entered empty. | | 21 Aug 2020 15:00:38 |



FDA-CBER-2022-1614-1684122

**US3292241**
**Folder: Screening**
**Form: Medical History (25)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:00:02 |
| User entered '0' | | 21 Aug 2020 15:00:38 |



FDA-CBER-2022-1614-1684123

**US3292241**
**Folder: Screening**
**Form: Medical History (25)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2015' | System | 21 Aug 2020 15:00:38 |

**US3292241**
**Folder: Screening**
**Form: Medical History (25)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2015' | System | 21 Aug 2020 15:00:38 |



FDA-CBER-2022-1614-1684125

**US3292241**
**Folder: Screening**
**Form: Medical History (25)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:00:38 |



FDA-CBER-2022-1614-1684126

**US3292241**
**Folder: Screening**
**Form: Medical History (25)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:00:38 |

**US3292241**
**Folder: Screening**
**Form: Medical History (26)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:00:19 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:05:14 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:05:14 |
| Data point term sent to Coder | System | 21 Aug 2020 15:03:18 |
| User entered 'Urinary incontinence' | (b) (4), (b) (6) | 21 Aug 2020 15:02:20 |



FDA-CBER-2022-1614-1684128

**US3292241**
**Folder: Screening**
**Form: Medical History (26)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:00:20 |
| User entered 'un UNK 2000' | | 21 Aug 2020 15:02:20 |



FDA-CBER-2022-1614-1684129

**US3292241**
**Folder: Screening**
**Form: Medical History (26)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:00:22 |
| User entered '0' | | 21 Aug 2020 15:02:20 |



FDA-CBER-2022-1614-1684130

**US3292241**
**Folder: Screening**
**Form: Medical History (26)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:00:24 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:02:20 |



FDA-CBER-2022-1614-1684131

**US3292241**
**Folder: Screening**
**Form: Medical History (26)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:00:25 |
| User entered empty. | | 21 Aug 2020 15:02:20 |



FDA-CBER-2022-1614-1684132

**US3292241**
**Folder: Screening**
**Form: Medical History (26)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:00:26 |
| User entered '0' | | 21 Aug 2020 15:02:20 |



FDA-CBER-2022-1614-1684133

**US3292241**
**Folder: Screening**
**Form: Medical History (26)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 15:02:20 |

**US3292241**
**Folder: Screening**
**Form: Medical History (26)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 15:02:20 |



FDA-CBER-2022-1614-1684135

**US3292241**
**Folder: Screening**
**Form: Medical History (26)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:02:20 |



FDA-CBER-2022-1614-1684136

**US3292241**
**Folder: Screening**
**Form: Medical History (26)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:02:20 |



FDA-CBER-2022-1614-1684137

**US3292241**
**Folder: Screening**
**Form: Medical History (27)**
**Generated On: 11 Aug 2021 22:21:07**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:00:48 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:05:15 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:05:15 |
| Data point term sent to Coder | System | 21 Aug 2020 15:03:19 |
| User entered 'Uterine fibroids' | (b) (4), (b) (6) | 21 Aug 2020 15:02:49 |



FDA-CBER-2022-1614-1684138

**US3292241**
**Folder: Screening**
**Form: Medical History (27)**
**Generated On: 11 Aug 2021 22:21:07**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:00:51 |
| User entered 'un UNK 1973' | | 21 Aug 2020 15:02:49 |



FDA-CBER-2022-1614-1684139

**US3292241**
**Folder: Screening**
**Form: Medical History (27)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:00:53 |
| User entered '0' | | 21 Aug 2020 15:02:49 |



FDA-CBER-2022-1614-1684140

**US3292241**
**Folder: Screening**
**Form: Medical History (27)**
**Generated On: 11 Aug 2021 22:21:07**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:01:01 |
| User entered 'No (N)' | | 21 Aug 2020 15:02:49 |

**US3292241**
**Folder: Screening**
**Form: Medical History (27)**
**Generated On: 11 Aug 2021 22:21:07**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:01:06 |
| User entered 'un UNK 2000' | | 21 Aug 2020 15:02:49 |



FDA-CBER-2022-1614-1684142

**US3292241**
**Folder: Screening**
**Form: Medical History (27)**
**Generated On: 11 Aug 2021 22:21:07**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:01:11 |
| User entered '0' | | 21 Aug 2020 15:02:49 |



FDA-CBER-2022-1614-1684143

**US3292241**
**Folder: Screening**
**Form: Medical History (27)**
**Generated On: 11 Aug 2021 22:21:07**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 1973' | System | 21 Aug 2020 15:02:49 |

**US3292241**
**Folder: Screening**
**Form: Medical History (27)**
**Generated On: 11 Aug 2021 22:21:07**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1973' | System | 21 Aug 2020 15:02:49 |



FDA-CBER-2022-1614-1684145

**US3292241**
**Folder: Screening**
**Form: Medical History (27)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'Jan 2000' | System | 21 Aug 2020 15:02:49 |

**US3292241**
**Folder: Screening**
**Form: Medical History (27)**
**Generated On: 11 Aug 2021 22:21:07**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2000' | System | 21 Aug 2020 15:02:49 |



FDA-CBER-2022-1614-1684147

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:41:57 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684148

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:41:57 |
| User entered '20 Aug 2020' | | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684149

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:41:57 |
| User entered '09:05' | | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684150

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '20 Aug 2020 09:05' | System | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684151

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Height *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:41:57 |
| User entered '163.3' cm | | 21 Aug 2020 15:03:54 |
| DataPoint set to visible. | System | 20 Aug 2020 17:17:36 |



FDA-CBER-2022-1614-1684152

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Weight *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:41:57 |
| User entered '72.4' kg | | 21 Aug 2020 15:03:54 |
| DataPoint set to visible. | System | 20 Aug 2020 17:17:36 |



FDA-CBER-2022-1614-1684153

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
BMI *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: User entered '27.14977' | System | 17 Sep 2020 00:15:47 |
| User entered '27.1' | System | 21 Aug 2020 15:03:54 |
| DataPoint set to visible. | System | 20 Aug 2020 17:17:36 |



FDA-CBER-2022-1614-1684154

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
BMI units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'kg/m2' | System | 21 Aug 2020 15:03:54 |
| DataPoint set to visible. | System | 20 Aug 2020 17:17:36 |



FDA-CBER-2022-1614-1684155

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:41:57 |
| User closed query ' Per CDM: Response noted; however 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). | | 29 Sep 2020 14:21:40 |
| Query ' Per CDM: Response noted; however 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). | Victoria Hernandez (b) (4) (b) (4) | 22 Sep 2020 18:21:38 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 22 Sep 2020 18:21:33 |
| User opened query ' Per CDM: Response noted; however 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) | 24 Aug 2020 19:07:26 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 24 Aug 2020 17:32:59 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | | 21 Aug 2020 15:04:21 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 21 Aug 2020 15:03:54 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684156

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:41:57 |
| User entered empty. | | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684157

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:41:57 |
| User entered empty. | | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684158

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:41:57 |
| User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | | 28 Oct 2020 10:51:41 |
| Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'UPDATED' (Site from DM). | | 07 Oct 2020 18:04:24 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | | 07 Oct 2020 18:04:07 |
| User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | | 07 Oct 2020 12:51:02 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 24 Aug 2020 17:33:01 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | | 21 Aug 2020 15:04:20 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 21 Aug 2020 15:03:54 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684159

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'bpm' | System | 07 Oct 2020 18:04:07 |
| User entered empty. | System | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684160

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:41:57 |
| User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | | 28 Oct 2020 10:52:00 |
| Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'UPDATED' (Site from DM). | | 07 Oct 2020 18:04:28 |
| User entered missing code ND - Not Done; reason fo change Data Entry Error | | 07 Oct 2020 18:04:07 |
| User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | | 07 Oct 2020 12:51:07 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 24 Aug 2020 17:33:04 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | | 21 Aug 2020 15:04:18 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 21 Aug 2020 15:03:54 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684161

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'breaths/min' | System | 07 Oct 2020 18:04:07 |
| User entered empty. | System | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684162

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:41:57 |
| User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | | 28 Oct 2020 10:52:23 |
| Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'UPDATED' (Site from DM). | | 07 Oct 2020 18:04:32 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | | 07 Oct 2020 18:04:07 |
| User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | | 07 Oct 2020 12:51:12 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 24 Aug 2020 17:33:15 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | | 21 Aug 2020 15:04:16 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 21 Aug 2020 15:03:54 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684163

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'mmHg' | System | 07 Oct 2020 18:04:07 |
| User entered empty. | System | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684164

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 19:41:57 |
| User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | | 28 Oct 2020 10:52:44 |
| Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'UPDATED' (Site from DM). | | 07 Oct 2020 18:04:36 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | | 07 Oct 2020 18:04:07 |
| User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | | 07 Oct 2020 12:51:20 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 24 Aug 2020 17:33:13 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | | 21 Aug 2020 15:04:12 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 21 Aug 2020 15:03:54 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684165

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'mmHg' | System | 07 Oct 2020 18:04:07 |
| User entered empty. | System | 21 Aug 2020 15:03:54 |



FDA-CBER-2022-1614-1684166

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Height (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684167

**US3292241**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Weight (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684168

**US3292241**
**Folder: Screening**
**Form: Physical Examination**
**Generated On: 11 Aug 2021 22:21:07**
Was the physical examination performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:42:29 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:04:45 |



FDA-CBER-2022-1614-1684169

**US3292241**
**Folder: Screening**
**Form: Physical Examination**
**Generated On: 11 Aug 2021 22:21:07**
Date of examination *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:42:29 |
| User entered '20 Aug 2020' | | 21 Aug 2020 15:04:45 |



FDA-CBER-2022-1614-1684170

**US3292241**
**Folder: Screening**
**Form: Childbearing Potential**
**Generated On: 11 Aug 2021 22:21:07**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:36:36 |
| DataPoint Un-verified. | | 08 Feb 2021 16:36:16 |
| DataPoint Verified. | | 08 Feb 2021 16:36:13 |
| User entered '20 Aug 2020' | | 21 Aug 2020 15:05:10 |



FDA-CBER-2022-1614-1684171

**US3292241**
**Folder: Screening**
**Form: Childbearing Potential**
**Generated On: 11 Aug 2021 22:21:07**
Is the participant of childbearing potential?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:36:18 |
| User entered 'No (N)' | | 21 Aug 2020 15:05:10 |



FDA-CBER-2022-1614-1684172

**US3292241**
**Folder: Screening**
**Form: Childbearing Potential**
**Generated On: 11 Aug 2021 22:21:07**
If No, what is the reason?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:36:19 |
| User entered 'Surgically sterile (SURGICALLY STERILE)' | | 21 Aug 2020 15:05:10 |



FDA-CBER-2022-1614-1684173

**US3292241**
**Folder: Screening**
**Form: Childbearing Potential**
**Generated On: 11 Aug 2021 22:21:07**
If Partner medically sterile or Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 31 Mar 2021 20:51:30 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 15:05:10 |



FDA-CBER-2022-1614-1684174

**US3292241**
**Folder: Screening**
**Form: Childbearing Potential**
**Generated On: 11 Aug 2021 22:21:07**
If Surgically sterile, date of surgery *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 16:36:21 |
| User entered 'un UNK 2000' | | 21 Aug 2020 15:05:10 |



FDA-CBER-2022-1614-1684175

**US3292241**
**Folder: Screening**
**Form: Childbearing Potential**
**Generated On: 11 Aug 2021 22:21:07**
Date of surgery unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 31 Mar 2021 20:51:30 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 15:05:10 |



FDA-CBER-2022-1614-1684176

**US3292241**
**Folder: Screening**
**Form: Childbearing Potential**
**Generated On: 11 Aug 2021 22:21:07**
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 31 Mar 2021 20:51:30 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 15:05:10 |



FDA-CBER-2022-1614-1684177

**US3292241**
**Folder: Screening**
**Form: Childbearing Potential**
**Generated On: 11 Aug 2021 22:21:07**
Date of last menstruation unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 31 Mar 2021 20:51:30 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 15:05:10 |



FDA-CBER-2022-1614-1684178

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:06:04 |



FDA-CBER-2022-1614-1684179

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered 'No (N)' | | 21 Aug 2020 15:06:04 |



FDA-CBER-2022-1614-1684180

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**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) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered 'No (N)' | | 21 Aug 2020 15:06:04 |



FDA-CBER-2022-1614-1684181

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**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) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered 'No (N)' | | 21 Aug 2020 15:06:04 |

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered 'No (N)' | | 21 Aug 2020 15:06:04 |

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**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) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered 'No (N)' | | 21 Aug 2020 15:06:04 |

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**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) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered 'No (N)' | | 21 Aug 2020 15:06:04 |

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**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) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered 'No (N)' | | 21 Aug 2020 15:06:04 |

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**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) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered 'No (N)' | | 21 Aug 2020 15:06:04 |



FDA-CBER-2022-1614-1684187

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**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) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered 'No (N)' | | 21 Aug 2020 15:06:04 |



FDA-CBER-2022-1614-1684188

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**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) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered 'No (N)' | | 21 Aug 2020 15:06:04 |

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**Other**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered 'No (N)' | | 21 Aug 2020 15:06:04 |



FDA-CBER-2022-1614-1684190

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**Specify**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered empty. | | 21 Aug 2020 15:06:04 |



FDA-CBER-2022-1614-1684191

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**No Risk Identified**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 15:06:04 |

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**Resides in Nursing Home or Assisted Living Facility**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered '0' | | 21 Aug 2020 15:06:04 |



FDA-CBER-2022-1614-1684193

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**

**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) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered '0' | | 21 Aug 2020 15:06:04 |



FDA-CBER-2022-1614-1684194

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**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) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered '0' | | 21 Aug 2020 15:06:04 |



FDA-CBER-2022-1614-1684195

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**

**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) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered '0' | | 21 Aug 2020 15:06:04 |



FDA-CBER-2022-1614-1684196

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**Resides in a single family home** (i.e., detached housing)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered '1' | | 21 Aug 2020 15:06:04 |

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**Other**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 15:06:04 |

**US3292241**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 11 Aug 2021 22:21:07**
**Specify**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:08 |
| User entered empty. | | 21 Aug 2020 15:06:04 |



FDA-CBER-2022-1614-1684199

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was this visit performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:15 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24SEP2020 is reported under Visit 2 Day 29visit 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). | | 24 Nov 2020 09:53:45 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24SEP2020 is reported under Visit 2 Day 29visit 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. ' answered with 'updated' (Site from DM). | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:18:05 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24SEP2020 is reported under Visit 2 Day 29visit 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) | 21 Oct 2020 11:50:35 |
| User entered 'Yes (Y)' | | 21 Aug 2020 16:19:19 |



FDA-CBER-2022-1614-1684200

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:15 |
| User entered '20 Aug 2020' | | 21 Aug 2020 16:19:19 |



FDA-CBER-2022-1614-1684201

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:15 |
| User entered 'Clinic (Clinic)' | | 21 Aug 2020 16:19:19 |



FDA-CBER-2022-1614-1684202

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Folder OID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'VISIT1' | System | 21 Aug 2020 16:19:19 |

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 11 Aug 2021 22:21:07**
What was the date of randomization? *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:43 |
| User entered '20 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 16:59:42 |



FDA-CBER-2022-1614-1684204

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 11 Aug 2021 22:21:07**
What was the participant's randomization number?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:43 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Aug 2020 05:49:57 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 05:49:57 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Aug 2020 16:59:42 |
| User entered '187240' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 16:59:42 |



FDA-CBER-2022-1614-1684205

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 11 Aug 2021 22:21:07**
In what Cohort was the participant enrolled?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:43 |
| User entered '>=65 years (3)' | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 16:59:42 |



FDA-CBER-2022-1614-1684206

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:43 |
| User entered 'No (N)' | | 21 Aug 2020 16:19:31 |



FDA-CBER-2022-1614-1684207

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:43 |
| User entered 'No (N)' | | 21 Aug 2020 16:19:31 |



FDA-CBER-2022-1614-1684208

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 11 Aug 2021 22:21:07**
Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:43 |
| User entered 'No (N)' | | 21 Aug 2020 16:19:31 |



FDA-CBER-2022-1614-1684209

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 11 Aug 2021 22:21:07**
Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:43 |
| User entered 'No (N)' | | 21 Aug 2020 16:19:31 |



FDA-CBER-2022-1614-1684210

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 11 Aug 2021 22:21:07**
Liver Disease

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:43 |
| User entered 'No (N)' | | 21 Aug 2020 16:19:31 |



FDA-CBER-2022-1614-1684211

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 11 Aug 2021 22:21:07**
Human Immunodeficiency Virus (HIV) infection

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:36:46 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 01:42:46 |



FDA-CBER-2022-1614-1684212

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Generated On: 11 Aug 2021 22:21:07**
Height

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:52 |
| User entered missing code ND - Not Done. | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684213

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Generated On: 11 Aug 2021 22:21:07**
Weight

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:54 |
| User entered missing code ND - Not Done. | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684214

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Generated On: 11 Aug 2021 22:21:07**
Height

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:52 |
| User entered missing code ND - Not Done. | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684215

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Generated On: 11 Aug 2021 22:21:07**
Weight

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:54 |
| User entered missing code ND - Not Done. | | 21 Aug 2020 16:20:45 |

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Timepoint

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User accepted default value 'Pre-Dose (PREDOSE)' | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684217

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered 'Yes (Y)' | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684218

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '20 Aug 2020' | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684219

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '10:40' | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684220

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered '20 Aug 2020 10:40' | System | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684221

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '36.8' C | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684222

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered 'Oral (Oral)' | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684223

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered empty. | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684224

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '76' | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684225

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'bpm' | System | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684226

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '16' | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684227

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'breaths/min' | System | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684228

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '142' | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684229

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'mmHg' | System | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684230

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '93' | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684231

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'mmHg' | System | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684232

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Generated On: 11 Aug 2021 22:21:07**
Height

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:52 |
| User entered missing code ND - Not Done. | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684233

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Generated On: 11 Aug 2021 22:21:07**
Weight

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:43:54 |
| User entered missing code ND - Not Done. | | 21 Aug 2020 16:20:45 |



FDA-CBER-2022-1614-1684234

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Timepoint

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User accepted default value 'Post-Dose (POSTDOSE)' | | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684235

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered 'Yes (Y)' | | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684236

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '20 Aug 2020' | | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684237

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '12:45' | | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684238

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered '20 Aug 2020 12:45' | System | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684239

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '36.5' C | | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684240

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered 'Oral (Oral)' | | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684241

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered empty. | | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684242

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '63' | | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684243

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'bpm' | System | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684244

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '16' | | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684245

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'breaths/min' | System | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684246

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '150' | | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684247

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'mmHg' | System | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684248

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:21 |
| User entered '93' | | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684249

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'mmHg' | System | 21 Aug 2020 16:21:37 |



FDA-CBER-2022-1614-1684250

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Physical Examination**
**Generated On: 11 Aug 2021 22:21:07**
Was the physical examination performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:26 |
| User entered 'No (N)' | | 21 Aug 2020 16:21:44 |



FDA-CBER-2022-1614-1684251

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Physical Examination**
**Generated On: 11 Aug 2021 22:21:07**
Date of examination *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:26 |
| User entered empty. | | 21 Aug 2020 16:21:44 |



FDA-CBER-2022-1614-1684252

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
Was study treatment given?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:41 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684253

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
If No, reason not given

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:41 |
| User entered empty. | Nathan Cortez (b) (4) | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684254

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:41 |
| User entered empty. | Nathan Cortez (b) (4) | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684255

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
What was the study treatment?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684256

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
What was the treatment date? *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:41 |
| User entered '20 Aug 2020' | Nathan Cortez (b) (4) | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684257

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
What was the treatment time? *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:41 |
| User entered '12:08' | Nathan Cortez (b) (4) | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684258

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
Treatment Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered '20 Aug 2020 12:08' | System | 20 Aug 2020 17:18:12 |

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:41 |
| User entered 'Left Arm (LEFT ARM)' | Nathan Cortez (b) (4) | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684260

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| DataPoint Verified. | | 10 Feb 2021 19:44:41 |
| User entered 'ONCE' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684261

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'INTRAMUSCULAR' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684262

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:59 |
| User entered 'Yes (Y)' | | 21 Aug 2020 16:22:15 |



FDA-CBER-2022-1614-1684263

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Collection date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:59 |
| User entered '20 Aug 2020' | | 21 Aug 2020 16:22:15 |



FDA-CBER-2022-1614-1684264

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Collection time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:44:59 |
| User entered '10:52' | | 21 Aug 2020 16:22:15 |



FDA-CBER-2022-1614-1684265

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered '20 Aug 2020 10:52' | System | 21 Aug 2020 16:22:15 |



FDA-CBER-2022-1614-1684266

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab**
**Generated On: 11 Aug 2021 22:21:07**
Collection date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:45:11 |
| User entered '20 Aug 2020' | | 21 Aug 2020 16:22:36 |



FDA-CBER-2022-1614-1684267

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 11 Aug 2021 22:21:07**
Lab Test

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | | 21 Aug 2020 16:22:36 |



FDA-CBER-2022-1614-1684268

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 11 Aug 2021 22:21:07**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:45:11 |
| User entered 'Yes (Y)' | | 21 Aug 2020 16:22:36 |



FDA-CBER-2022-1614-1684269

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 11 Aug 2021 22:21:07**
Collection time *(00:00 - 23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:45:11 |
| User entered '11:21' | | 21 Aug 2020 16:22:36 |



FDA-CBER-2022-1614-1684270

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 11 Aug 2021 22:21:07**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '20 Aug 2020 11:21' | System | 21 Aug 2020 16:22:36 |



FDA-CBER-2022-1614-1684271

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 11 Aug 2021 22:21:07**
Lab Test

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | | 21 Aug 2020 16:22:44 |



FDA-CBER-2022-1614-1684272

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 11 Aug 2021 22:21:07**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:45:11 |
| User entered 'No (N)' | | 21 Aug 2020 16:22:44 |

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 11 Aug 2021 22:21:07**
Collection time *(00:00 - 23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:45:11 |
| User entered empty. | | 21 Aug 2020 16:22:44 |



FDA-CBER-2022-1614-1684274

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 11 Aug 2021 22:21:07**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 16:22:44 |



FDA-CBER-2022-1614-1684275

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:45:50 |
| User closed query 'Per GCL Lab Recon: it appears GCL has a Swab Sample with date 24SEP2020 in Visit 2 Day29 ; however there is no record in EDC. Please reconcile or clarify.<br><br>' (Site from DM). | | 17 Nov 2020 12:44:15 |
| Query 'Per GCL Lab Recon: it appears GCL has a Swab Sample with date 24SEP2020 in Visit 2 Day29 ; however there is no record in EDC. Please reconcile or clarify.<br><br>' answered with 'updated' (Site from DM). | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:17:52 |
| User opened query 'Per GCL Lab Recon: it appears GCL has a Swab Sample with date 24SEP2020 in Visit 2 Day29 ; however there is no record in EDC. Please reconcile or clarify.<br><br>' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 11:28:55 |
| User entered 'Yes (Y)' | | 21 Aug 2020 16:22:51 |



FDA-CBER-2022-1614-1684276

**US3292241**
**Folder: Visit 1 Day 1**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered '1' | System | 21 Aug 2020 16:22:51 |



FDA-CBER-2022-1614-1684277

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684278

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:49:48', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'c9dcb414-b766-45ea-bccd-bf00bae3a247' | System | 20 Aug 2020 17:50:10 |
| User entered 'Yes (Y)' | System | 20 Aug 2020 17:50:10 |



FDA-CBER-2022-1614-1684279

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:49:57', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'c9dcb414-b766-45ea-bccd-bf00bae3a247' | System | 20 Aug 2020 17:50:10 |
| User entered '97.7' | System | 20 Aug 2020 17:50:10 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:02', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'c9dcb414-b766-45ea-bccd-bf00bae3a247' | System | 20 Aug 2020 17:50:10 |
| User entered 'No (N)' | System | 20 Aug 2020 17:50:10 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:07', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'c9dcb414-b766-45ea-bccd-bf00bae3a247' | System | 20 Aug 2020 17:50:10 |
| User entered '20 Aug 2020 12:50' | System | 20 Aug 2020 17:50:10 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '20 Aug 2020 12:28' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684283

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '20 Aug 2020 14:58' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684284

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684285

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:55:53', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0b0070b6-f61b-4d61-b261-a53b252a326f' | System | 20 Aug 2020 23:56:37 |
| User entered 'Yes (Y)' | System | 20 Aug 2020 23:56:37 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:56:04', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0b0070b6-f61b-4d61-b261-a53b252a326f' | System | 20 Aug 2020 23:56:37 |
| User entered '99.4' | System | 20 Aug 2020 23:56:37 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:56:11', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0b0070b6-f61b-4d61-b261-a53b252a326f' | System | 20 Aug 2020 23:56:37 |
| User entered 'Yes (Y)' | System | 20 Aug 2020 23:56:37 |



FDA-CBER-2022-1614-1684288

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| 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). | | 01 Sep 2020 19:14:33 |
| 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 'Subject states he took Tylenol (500 mg) for Headache and bodyaches , and temperature ' (Site from System). | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 21:57:16 |
| 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 | 20 Aug 2020 23:56:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:56:18', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0b0070b6-f61b-4d61-b261-a53b252a326f' | System | 20 Aug 2020 23:56:37 |
| User entered '1' | System | 20 Aug 2020 23:56:37 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:56:18', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0b0070b6-f61b-4d61-b261-a53b252a326f' | System | 20 Aug 2020 23:56:37 |
| User entered '0' | System | 20 Aug 2020 23:56:37 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:56:34', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0b0070b6-f61b-4d61-b261-a53b252a326f' | System | 20 Aug 2020 23:56:37 |
| User entered '20 Aug 2020 18:56' | System | 20 Aug 2020 23:56:37 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '20 Aug 2020 15:53' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684292

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684293

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 2' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684294

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:05:20', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '6a767110-880f-4cac-bdc9-f7c6bacb4f85' | System | 21 Aug 2020 21:06:06 |
| User entered 'Yes (Y)' | System | 21 Aug 2020 21:06:06 |



FDA-CBER-2022-1614-1684295

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:05:51', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '6a767110-880f-4cac-bdc9-f7c6bacb4f85' | System | 21 Aug 2020 21:06:06 |
| User entered '98.7' | System | 21 Aug 2020 21:06:06 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:05:56', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '6a767110-880f-4cac-bdc9-f7c6bacb4f85' | System | 21 Aug 2020 21:06:06 |
| User entered 'No (N)' | System | 21 Aug 2020 21:06:06 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:06:02', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '6a767110-880f-4cac-bdc9-f7c6bacb4f85' | System | 21 Aug 2020 21:06:06 |
| User entered '21 Aug 2020 16:06' | System | 21 Aug 2020 21:06:06 |



FDA-CBER-2022-1614-1684298

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684299

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684300

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 3' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684301

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:12:06', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '40a0bb2e-c80a-4abc-a2c0-2a544f059059' | System | 22 Aug 2020 21:13:00 |
| User entered 'Yes (Y)' | System | 22 Aug 2020 21:13:00 |



FDA-CBER-2022-1614-1684302

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:12:32', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '40a0bb2e-c80a-4abc-a2c0-2a544f059059' | System | 22 Aug 2020 21:13:00 |
| User entered '98.6' | System | 22 Aug 2020 21:13:00 |



FDA-CBER-2022-1614-1684303

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:12:36', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '40a0bb2e-c80a-4abc-a2c0-2a544f059059' | System | 22 Aug 2020 21:13:00 |
| User entered 'No (N)' | System | 22 Aug 2020 21:13:00 |



FDA-CBER-2022-1614-1684304

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:12:58', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '40a0bb2e-c80a-4abc-a2c0-2a544f059059' | System | 22 Aug 2020 21:13:00 |
| User entered '22 Aug 2020 16:12' | System | 22 Aug 2020 21:13:00 |



FDA-CBER-2022-1614-1684305

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684306

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684307

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 4' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684308

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:14:56', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd7cf5bb3-8784-4c20-85a2-e45ac4700cad' | System | 23 Aug 2020 22:15:52 |
| User entered 'Yes (Y)' | System | 23 Aug 2020 22:15:52 |



FDA-CBER-2022-1614-1684309

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:15:04', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd7cf5bb3-8784-4c20-85a2-e45ac4700cad' | System | 23 Aug 2020 22:15:52 |
| User entered '97.7' | System | 23 Aug 2020 22:15:52 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:15:46', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd7cf5bb3-8784-4c20-85a2-e45ac4700cad' | System | 23 Aug 2020 22:15:52 |
| User entered 'No (N)' | System | 23 Aug 2020 22:15:52 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:15:51', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd7cf5bb3-8784-4c20-85a2-e45ac4700cad' | System | 23 Aug 2020 22:15:52 |
| User entered '23 Aug 2020 17:15' | System | 23 Aug 2020 22:15:52 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684313

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684314

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 5' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684315

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:31:40', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '14704c34-642e-43d2-ad53-904337b69ce5' | System | 24 Aug 2020 20:32:08 |
| User entered 'Yes (Y)' | System | 24 Aug 2020 20:32:08 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:31:48', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '14704c34-642e-43d2-ad53-904337b69ce5' | System | 24 Aug 2020 20:32:08 |
| User entered '99.4' | System | 24 Aug 2020 20:32:08 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:31:51', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '14704c34-642e-43d2-ad53-904337b69ce5' | System | 24 Aug 2020 20:32:08 |
| User entered 'Yes (Y)' | System | 24 Aug 2020 20:32:08 |



FDA-CBER-2022-1614-1684318

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| 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). | | 01 Sep 2020 19:14:46 |
| 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 'Subject states he took Tylenol (500 mg) for Headache and bodyaches ' (Site from System). | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 21:55:55 |
| 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 | 24 Aug 2020 20:32:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:31:59', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '14704c34-642e-43d2-ad53-904337b69ce5' | System | 24 Aug 2020 20:32:08 |
| User entered '1' | System | 24 Aug 2020 20:32:08 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:31:59', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '14704c34-642e-43d2-ad53-904337b69ce5' | System | 24 Aug 2020 20:32:08 |
| User entered '0' | System | 24 Aug 2020 20:32:08 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:32:04', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '14704c34-642e-43d2-ad53-904337b69ce5' | System | 24 Aug 2020 20:32:08 |
| User entered '24 Aug 2020 15:32' | System | 24 Aug 2020 20:32:08 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684322

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684323

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 6' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684324

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:47:29', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'a93dfd19-5494-4110-93a9-4074c1e603c3' | System | 25 Aug 2020 21:48:58 |
| User entered 'Yes (Y)' | System | 25 Aug 2020 21:48:58 |



FDA-CBER-2022-1614-1684325

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:48:38', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'a93dfd19-5494-4110-93a9-4074c1e603c3' | System | 25 Aug 2020 21:48:58 |
| User entered '98.9' | System | 25 Aug 2020 21:48:58 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:48:44', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'a93dfd19-5494-4110-93a9-4074c1e603c3' | System | 25 Aug 2020 21:48:58 |
| User entered 'Yes (Y)' | System | 25 Aug 2020 21:48:58 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| 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). | | 01 Sep 2020 19:14:51 |
| 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 'Subject states he took Tylenol (500 mg) for Headache and bodyaches ' (Site from System). | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 21:56:42 |
| 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 | 25 Aug 2020 21:48:58 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:48:49', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'a93dfd19-5494-4110-93a9-4074c1e603c3' | System | 25 Aug 2020 21:48:58 |
| User entered '1' | System | 25 Aug 2020 21:48:58 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:48:49', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'a93dfd19-5494-4110-93a9-4074c1e603c3' | System | 25 Aug 2020 21:48:58 |
| User entered '0' | System | 25 Aug 2020 21:48:58 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:48:56', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'a93dfd19-5494-4110-93a9-4074c1e603c3' | System | 25 Aug 2020 21:48:58 |
| User entered '25 Aug 2020 16:48' | System | 25 Aug 2020 21:48:58 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684331

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684332

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 7' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684333

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:14:54', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '5b3affd1-eb9d-425f-9313-aca80b1228d6' | System | 26 Aug 2020 22:16:12 |
| User entered 'Yes (Y)' | System | 26 Aug 2020 22:16:12 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:15:55', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '5b3affd1-eb9d-425f-9313-aca80b1228d6' | System | 26 Aug 2020 22:16:12 |
| User entered '99.6' | System | 26 Aug 2020 22:16:12 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:16:00', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '5b3affd1-eb9d-425f-9313-aca80b1228d6' | System | 26 Aug 2020 22:16:12 |
| User entered 'Yes (Y)' | System | 26 Aug 2020 22:16:12 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| 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). | | 01 Sep 2020 19:14:57 |
| 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 'Subject states he took Tylenol (500 mg) for Headache and bodyaches and temperature ' (Site from System). | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 21:57:39 |
| 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 | 26 Aug 2020 22:16:12 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:16:05', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '5b3affd1-eb9d-425f-9313-aca80b1228d6' | System | 26 Aug 2020 22:16:12 |
| User entered '1' | System | 26 Aug 2020 22:16:12 |



FDA-CBER-2022-1614-1684337

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:16:05', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '5b3affd1-eb9d-425f-9313-aca80b1228d6' | System | 26 Aug 2020 22:16:12 |
| User entered '0' | System | 26 Aug 2020 22:16:12 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:16:10', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '5b3affd1-eb9d-425f-9313-aca80b1228d6' | System | 26 Aug 2020 22:16:12 |
| User entered '26 Aug 2020 17:16' | System | 26 Aug 2020 22:16:12 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684340

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684341

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 25 Aug 2020 21:48:58 |
| User entered 'Day 8' | System | 25 Aug 2020 21:48:58 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:02:34', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd9f6286f-587f-4ef8-9ef3-c958dd038c36' | System | 28 Aug 2020 00:02:59 |
| User entered 'Yes (Y)' | System | 28 Aug 2020 00:02:59 |



FDA-CBER-2022-1614-1684343

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:02:43', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd9f6286f-587f-4ef8-9ef3-c958dd038c36' | System | 28 Aug 2020 00:02:59 |
| User entered '98.8' | System | 28 Aug 2020 00:02:59 |



FDA-CBER-2022-1614-1684344

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:02:47', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd9f6286f-587f-4ef8-9ef3-c958dd038c36' | System | 28 Aug 2020 00:02:59 |
| User entered 'Yes (Y)' | System | 28 Aug 2020 00:02:59 |



FDA-CBER-2022-1614-1684345

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| 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). | | 01 Sep 2020 19:15:06 |
| 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 'Subject states he took Tylenol (500 mg) for Headache and bodyaches ' (Site from System). | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 21:58:17 |
| 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 Aug 2020 00:02:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:02:50', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd9f6286f-587f-4ef8-9ef3-c958dd038c36' | System | 28 Aug 2020 00:02:59 |
| User entered '1' | System | 28 Aug 2020 00:02:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:02:50', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd9f6286f-587f-4ef8-9ef3-c958dd038c36' | System | 28 Aug 2020 00:02:59 |
| User entered '0' | System | 28 Aug 2020 00:02:59 |



FDA-CBER-2022-1614-1684347

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:02:55', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd9f6286f-587f-4ef8-9ef3-c958dd038c36' | System | 28 Aug 2020 00:02:59 |
| User entered '27 Aug 2020 19:02' | System | 28 Aug 2020 00:02:59 |



FDA-CBER-2022-1614-1684348

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '27 Aug 2020 12:00' | System | 25 Aug 2020 21:48:58 |



FDA-CBER-2022-1614-1684349

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 11:59' | System | 25 Aug 2020 21:48:58 |



FDA-CBER-2022-1614-1684350

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 26 Aug 2020 22:16:12 |
| User entered 'Day 9' | System | 26 Aug 2020 22:16:12 |



FDA-CBER-2022-1614-1684351

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684352

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684353

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684354

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684355

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684356

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684357

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 22:16:12 |



FDA-CBER-2022-1614-1684358

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 22:16:12 |



FDA-CBER-2022-1614-1684359

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 28 Aug 2020 00:02:59 |
| User entered 'Day 10' | System | 28 Aug 2020 00:02:59 |



FDA-CBER-2022-1614-1684360

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684361

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684362

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684363

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684364

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684365

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684366

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 12:00' | System | 28 Aug 2020 00:02:59 |



FDA-CBER-2022-1614-1684367

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '30 Aug 2020 11:59' | System | 28 Aug 2020 00:02:59 |



FDA-CBER-2022-1614-1684368

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684369

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:16', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '79feeeac-1414-4886-ba18-e52af863ebd5' | System | 20 Aug 2020 17:50:35 |
| User entered 'None (1)' | System | 20 Aug 2020 17:50:35 |



FDA-CBER-2022-1614-1684370

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:20', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '79feeeac-1414-4886-ba18-e52af863ebd5' | System | 20 Aug 2020 17:50:35 |
| User entered 'No (N)' | System | 20 Aug 2020 17:50:35 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:23', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '79feeeac-1414-4886-ba18-e52af863ebd5' | System | 20 Aug 2020 17:50:35 |
| User entered 'No (N)' | System | 20 Aug 2020 17:50:35 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:27', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '79feeeac-1414-4886-ba18-e52af863ebd5' | System | 20 Aug 2020 17:50:35 |
| User entered 'None (1)' | System | 20 Aug 2020 17:50:35 |



FDA-CBER-2022-1614-1684373

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:31', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '79feeeac-1414-4886-ba18-e52af863ebd5' | System | 20 Aug 2020 17:50:35 |
| User entered '20 Aug 2020 12:50' | System | 20 Aug 2020 17:50:35 |



FDA-CBER-2022-1614-1684374

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '20 Aug 2020 12:28' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684375

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '20 Aug 2020 14:58' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684376

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684377

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:57:43', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '288869ec-2df9-40a4-8c55-34648beb6294' | System | 20 Aug 2020 23:58:12 |
| User entered 'Does not interfere with activity (2)' | System | 20 Aug 2020 23:58:12 |



FDA-CBER-2022-1614-1684378

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:57:47', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '288869ec-2df9-40a4-8c55-34648beb6294' | System | 20 Aug 2020 23:58:12 |
| User entered 'No (N)' | System | 20 Aug 2020 23:58:12 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:57:51', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '288869ec-2df9-40a4-8c55-34648beb6294' | System | 20 Aug 2020 23:58:12 |
| User entered 'No (N)' | System | 20 Aug 2020 23:58:12 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:58:00', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '288869ec-2df9-40a4-8c55-34648beb6294' | System | 20 Aug 2020 23:58:12 |
| User entered 'None (1)' | System | 20 Aug 2020 23:58:12 |



FDA-CBER-2022-1614-1684381

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:58:08', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '288869ec-2df9-40a4-8c55-34648beb6294' | System | 20 Aug 2020 23:58:12 |
| User entered '20 Aug 2020 18:58' | System | 20 Aug 2020 23:58:12 |



FDA-CBER-2022-1614-1684382

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '20 Aug 2020 15:53' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684383

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684384

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 2' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684385

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:06:13', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '093ac24e-92a6-4006-b591-cbebe5223e76' | System | 21 Aug 2020 21:07:32 |
| User entered 'Does not interfere with activity (2)' | System | 21 Aug 2020 21:07:32 |



FDA-CBER-2022-1614-1684386

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:07:05', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '093ac24e-92a6-4006-b591-cbebe5223e76' | System | 21 Aug 2020 21:07:32 |
| User entered 'No (N)' | System | 21 Aug 2020 21:07:32 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:07:11', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '093ac24e-92a6-4006-b591-cbebe5223e76' | System | 21 Aug 2020 21:07:32 |
| User entered 'No (N)' | System | 21 Aug 2020 21:07:32 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:07:19', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '093ac24e-92a6-4006-b591-cbebe5223e76' | System | 21 Aug 2020 21:07:32 |
| User entered 'None (1)' | System | 21 Aug 2020 21:07:32 |



FDA-CBER-2022-1614-1684389

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:07:28', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '093ac24e-92a6-4006-b591-cbebe5223e76' | System | 21 Aug 2020 21:07:32 |
| User entered '21 Aug 2020 16:07' | System | 21 Aug 2020 21:07:32 |



FDA-CBER-2022-1614-1684390

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684391

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684392

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 3' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684393

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:13:08', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'f7dbcbb2-7049-4b77-884c-1e7a236c3a3b' | System | 22 Aug 2020 21:13:36 |
| User entered 'None (1)' | System | 22 Aug 2020 21:13:36 |



FDA-CBER-2022-1614-1684394

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:13:13', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'f7dbcbb2-7049-4b77-884c-1e7a236c3a3b' | System | 22 Aug 2020 21:13:36 |
| User entered 'No (N)' | System | 22 Aug 2020 21:13:36 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:13:21', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'f7dbcbb2-7049-4b77-884c-1e7a236c3a3b' | System | 22 Aug 2020 21:13:36 |
| User entered 'No (N)' | System | 22 Aug 2020 21:13:36 |



FDA-CBER-2022-1614-1684396

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:13:30', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'f7dbcbb2-7049-4b77-884c-1e7a236c3a3b' | System | 22 Aug 2020 21:13:36 |
| User entered 'None (1)' | System | 22 Aug 2020 21:13:36 |



FDA-CBER-2022-1614-1684397

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:13:34', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'f7dbcbb2-7049-4b77-884c-1e7a236c3a3b' | System | 22 Aug 2020 21:13:36 |
| User entered '22 Aug 2020 16:13' | System | 22 Aug 2020 21:13:36 |



FDA-CBER-2022-1614-1684398

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684399

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684400

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 4' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684401

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:16:11', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '9c3d741c-d6ac-4b33-bc34-3657e94eadb9' | System | 23 Aug 2020 22:16:45 |
| User entered 'None (1)' | System | 23 Aug 2020 22:16:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:16:18', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '9c3d741c-d6ac-4b33-bc34-3657e94eadb9' | System | 23 Aug 2020 22:16:45 |
| User entered 'No (N)' | System | 23 Aug 2020 22:16:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:16:24', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '9c3d741c-d6ac-4b33-bc34-3657e94eadb9' | System | 23 Aug 2020 22:16:45 |
| User entered 'No (N)' | System | 23 Aug 2020 22:16:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:16:37', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '9c3d741c-d6ac-4b33-bc34-3657e94eadb9' | System | 23 Aug 2020 22:16:45 |
| User entered 'None (1)' | System | 23 Aug 2020 22:16:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:16:40', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '9c3d741c-d6ac-4b33-bc34-3657e94eadb9' | System | 23 Aug 2020 22:16:45 |
| User entered '23 Aug 2020 17:16' | System | 23 Aug 2020 22:16:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684407

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684408

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 5' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684409

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:32:10', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '15ab22bb-84cc-4d8b-b76c-9a84fad30d2e' | System | 24 Aug 2020 20:33:09 |
| User entered 'None (1)' | System | 24 Aug 2020 20:33:09 |



FDA-CBER-2022-1614-1684410

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:32:18', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '15ab22bb-84cc-4d8b-b76c-9a84fad30d2e' | System | 24 Aug 2020 20:33:09 |
| User entered 'No (N)' | System | 24 Aug 2020 20:33:09 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:32:53', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '15ab22bb-84cc-4d8b-b76c-9a84fad30d2e' | System | 24 Aug 2020 20:33:09 |
| User entered 'No (N)' | System | 24 Aug 2020 20:33:09 |



FDA-CBER-2022-1614-1684412

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:32:59', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '15ab22bb-84cc-4d8b-b76c-9a84fad30d2e' | System | 24 Aug 2020 20:33:09 |
| User entered 'None (1)' | System | 24 Aug 2020 20:33:09 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:33:05', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '15ab22bb-84cc-4d8b-b76c-9a84fad30d2e' | System | 24 Aug 2020 20:33:09 |
| User entered '24 Aug 2020 15:33' | System | 24 Aug 2020 20:33:09 |



FDA-CBER-2022-1614-1684414

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684415

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684416

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 6' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684417

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:49:03', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'f1daccf1-624c-4d66-9d44-64dda618a05a' | System | 25 Aug 2020 21:49:28 |
| User entered 'None (1)' | System | 25 Aug 2020 21:49:28 |



FDA-CBER-2022-1614-1684418

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:49:10', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'f1daccf1-624c-4d66-9d44-64dda618a05a' | System | 25 Aug 2020 21:49:28 |
| User entered 'No (N)' | System | 25 Aug 2020 21:49:28 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:49:14', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'f1daccf1-624c-4d66-9d44-64dda618a05a' | System | 25 Aug 2020 21:49:28 |
| User entered 'No (N)' | System | 25 Aug 2020 21:49:28 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:49:18', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'f1daccf1-624c-4d66-9d44-64dda618a05a' | System | 25 Aug 2020 21:49:28 |
| User entered 'None (1)' | System | 25 Aug 2020 21:49:28 |



FDA-CBER-2022-1614-1684421

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:49:25', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'f1daccf1-624c-4d66-9d44-64dda618a05a' | System | 25 Aug 2020 21:49:28 |
| User entered '25 Aug 2020 16:49' | System | 25 Aug 2020 21:49:28 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684423

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684424

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 7' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684425

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:16:22', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '4dd8069c-fa27-4a72-b68d-663da1165eee' | System | 26 Aug 2020 22:17:17 |
| User entered 'None (1)' | System | 26 Aug 2020 22:17:17 |



FDA-CBER-2022-1614-1684426

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:16:27', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '4dd8069c-fa27-4a72-b68d-663da1165eee' | System | 26 Aug 2020 22:17:17 |
| User entered 'No (N)' | System | 26 Aug 2020 22:17:17 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:16:59', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '4dd8069c-fa27-4a72-b68d-663da1165eee' | System | 26 Aug 2020 22:17:17 |
| User entered 'No (N)' | System | 26 Aug 2020 22:17:17 |



FDA-CBER-2022-1614-1684428

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:17:12', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '4dd8069c-fa27-4a72-b68d-663da1165eee' | System | 26 Aug 2020 22:17:17 |
| User entered 'None (1)' | System | 26 Aug 2020 22:17:17 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:17:15', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '4dd8069c-fa27-4a72-b68d-663da1165eee' | System | 26 Aug 2020 22:17:17 |
| User entered '26 Aug 2020 17:17' | System | 26 Aug 2020 22:17:17 |



FDA-CBER-2022-1614-1684430

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684431

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684432

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684433

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:41', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '3cea1f87-026c-4448-9f26-ab11b9457137' | System | 20 Aug 2020 17:51:05 |
| User entered 'None (0)' | System | 20 Aug 2020 17:51:05 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:44', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '3cea1f87-026c-4448-9f26-ab11b9457137' | System | 20 Aug 2020 17:51:05 |
| User entered 'None (0)' | System | 20 Aug 2020 17:51:05 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:47', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '3cea1f87-026c-4448-9f26-ab11b9457137' | System | 20 Aug 2020 17:51:05 |
| User entered 'None (0)' | System | 20 Aug 2020 17:51:05 |



FDA-CBER-2022-1614-1684436

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:49', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '3cea1f87-026c-4448-9f26-ab11b9457137' | System | 20 Aug 2020 17:51:05 |
| User entered 'None (0)' | System | 20 Aug 2020 17:51:05 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:51', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '3cea1f87-026c-4448-9f26-ab11b9457137' | System | 20 Aug 2020 17:51:05 |
| User entered 'None (0)' | System | 20 Aug 2020 17:51:05 |



FDA-CBER-2022-1614-1684438

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:53', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '3cea1f87-026c-4448-9f26-ab11b9457137' | System | 20 Aug 2020 17:51:05 |
| User entered 'None (0)' | System | 20 Aug 2020 17:51:05 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:50:58', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '3cea1f87-026c-4448-9f26-ab11b9457137' | System | 20 Aug 2020 17:51:05 |
| User entered 'No (N)' | System | 20 Aug 2020 17:51:05 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T12:51:01', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '3cea1f87-026c-4448-9f26-ab11b9457137' | System | 20 Aug 2020 17:51:05 |
| User entered '20 Aug 2020 12:51' | System | 20 Aug 2020 17:51:05 |



FDA-CBER-2022-1614-1684441

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '20 Aug 2020 12:28' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684442

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '20 Aug 2020 14:58' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684443

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684444

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:56:53', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'cd9d2492-23be-4280-946c-7aba4fa93687' | System | 20 Aug 2020 23:57:34 |
| User entered 'Any use of prescription pain reliever or prevents daily activity (3)' | System | 20 Aug 2020 23:57:34 |



FDA-CBER-2022-1614-1684445

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:57:03', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'cd9d2492-23be-4280-946c-7aba4fa93687' | System | 20 Aug 2020 23:57:34 |
| User entered 'No interference with activity (1)' | System | 20 Aug 2020 23:57:34 |



FDA-CBER-2022-1614-1684446

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:57:07', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'cd9d2492-23be-4280-946c-7aba4fa93687' | System | 20 Aug 2020 23:57:34 |
| User entered 'None (0)' | System | 20 Aug 2020 23:57:34 |



FDA-CBER-2022-1614-1684447

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:57:11', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'cd9d2492-23be-4280-946c-7aba4fa93687' | System | 20 Aug 2020 23:57:34 |
| User entered 'None (0)' | System | 20 Aug 2020 23:57:34 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:57:14', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'cd9d2492-23be-4280-946c-7aba4fa93687' | System | 20 Aug 2020 23:57:34 |
| User entered 'None (0)' | System | 20 Aug 2020 23:57:34 |



FDA-CBER-2022-1614-1684449

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:57:17', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'cd9d2492-23be-4280-946c-7aba4fa93687' | System | 20 Aug 2020 23:57:34 |
| User entered 'None (0)' | System | 20 Aug 2020 23:57:34 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:57:21', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'cd9d2492-23be-4280-946c-7aba4fa93687' | System | 20 Aug 2020 23:57:34 |
| User entered 'No (N)' | System | 20 Aug 2020 23:57:34 |



FDA-CBER-2022-1614-1684451

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-20T18:57:30', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'cd9d2492-23be-4280-946c-7aba4fa93687' | System | 20 Aug 2020 23:57:34 |
| User entered '20 Aug 2020 18:57' | System | 20 Aug 2020 23:57:34 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '20 Aug 2020 15:53' | System | 20 Aug 2020 17:18:12 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684454

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 2' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684455

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:07:44', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd8470fff-3791-422d-8c23-1711bfc94b4e' | System | 21 Aug 2020 21:08:27 |
| User entered 'No interference with activity (1)' | System | 21 Aug 2020 21:08:27 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:07:50', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd8470fff-3791-422d-8c23-1711bfc94b4e' | System | 21 Aug 2020 21:08:27 |
| User entered 'None (0)' | System | 21 Aug 2020 21:08:27 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:07:55', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd8470fff-3791-422d-8c23-1711bfc94b4e' | System | 21 Aug 2020 21:08:27 |
| User entered 'None (0)' | System | 21 Aug 2020 21:08:27 |



FDA-CBER-2022-1614-1684458

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:08:00', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd8470fff-3791-422d-8c23-1711bfc94b4e' | System | 21 Aug 2020 21:08:27 |
| User entered 'None (0)' | System | 21 Aug 2020 21:08:27 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:08:09', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd8470fff-3791-422d-8c23-1711bfc94b4e' | System | 21 Aug 2020 21:08:27 |
| User entered 'None (0)' | System | 21 Aug 2020 21:08:27 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:08:12', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd8470fff-3791-422d-8c23-1711bfc94b4e' | System | 21 Aug 2020 21:08:27 |
| User entered 'None (0)' | System | 21 Aug 2020 21:08:27 |



FDA-CBER-2022-1614-1684461

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:08:19', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd8470fff-3791-422d-8c23-1711bfc94b4e' | System | 21 Aug 2020 21:08:27 |
| User entered 'No (N)' | System | 21 Aug 2020 21:08:27 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-21T16:08:23', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd8470fff-3791-422d-8c23-1711bfc94b4e' | System | 21 Aug 2020 21:08:27 |
| User entered '21 Aug 2020 16:08' | System | 21 Aug 2020 21:08:27 |



FDA-CBER-2022-1614-1684463

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684464

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684465

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 3' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684466

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:13:44', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '19608ba3-fa8b-459b-aa21-4c527032351c' | System | 22 Aug 2020 21:14:25 |
| User entered 'No interference with activity (1)' | System | 22 Aug 2020 21:14:25 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:13:53', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '19608ba3-fa8b-459b-aa21-4c527032351c' | System | 22 Aug 2020 21:14:25 |
| User entered 'No interference with activity (1)' | System | 22 Aug 2020 21:14:25 |



FDA-CBER-2022-1614-1684468

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:13:57', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '19608ba3-fa8b-459b-aa21-4c527032351c' | System | 22 Aug 2020 21:14:25 |
| User entered 'None (0)' | System | 22 Aug 2020 21:14:25 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:14:05', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '19608ba3-fa8b-459b-aa21-4c527032351c' | System | 22 Aug 2020 21:14:25 |
| User entered 'None (0)' | System | 22 Aug 2020 21:14:25 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:14:08', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '19608ba3-fa8b-459b-aa21-4c527032351c' | System | 22 Aug 2020 21:14:25 |
| User entered 'None (0)' | System | 22 Aug 2020 21:14:25 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:14:11', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '19608ba3-fa8b-459b-aa21-4c527032351c' | System | 22 Aug 2020 21:14:25 |
| User entered 'None (0)' | System | 22 Aug 2020 21:14:25 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:14:14', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '19608ba3-fa8b-459b-aa21-4c527032351c' | System | 22 Aug 2020 21:14:25 |
| User entered 'No (N)' | System | 22 Aug 2020 21:14:25 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-22T16:14:21', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '19608ba3-fa8b-459b-aa21-4c527032351c' | System | 22 Aug 2020 21:14:25 |
| User entered '22 Aug 2020 16:14' | System | 22 Aug 2020 21:14:25 |



FDA-CBER-2022-1614-1684474

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684475

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684476

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 4' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684477

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:16:54', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '498a9abb-dd78-449c-8baa-b4f165a9d4c1' | System | 23 Aug 2020 22:17:53 |
| User entered 'No interference with activity (1)' | System | 23 Aug 2020 22:17:53 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:17:03', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '498a9abb-dd78-449c-8baa-b4f165a9d4c1' | System | 23 Aug 2020 22:17:53 |
| User entered 'No interference with activity (1)' | System | 23 Aug 2020 22:17:53 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:17:07', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '498a9abb-dd78-449c-8baa-b4f165a9d4c1' | System | 23 Aug 2020 22:17:53 |
| User entered 'None (0)' | System | 23 Aug 2020 22:17:53 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:17:15', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '498a9abb-dd78-449c-8baa-b4f165a9d4c1' | System | 23 Aug 2020 22:17:53 |
| User entered 'None (0)' | System | 23 Aug 2020 22:17:53 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:17:24', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '498a9abb-dd78-449c-8baa-b4f165a9d4c1' | System | 23 Aug 2020 22:17:53 |
| User entered 'None (0)' | System | 23 Aug 2020 22:17:53 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:17:30', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '498a9abb-dd78-449c-8baa-b4f165a9d4c1' | System | 23 Aug 2020 22:17:53 |
| User entered 'None (0)' | System | 23 Aug 2020 22:17:53 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:17:34', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '498a9abb-dd78-449c-8baa-b4f165a9d4c1' | System | 23 Aug 2020 22:17:53 |
| User entered 'No (N)' | System | 23 Aug 2020 22:17:53 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-23T17:17:39', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '498a9abb-dd78-449c-8baa-b4f165a9d4c1' | System | 23 Aug 2020 22:17:53 |
| User entered '23 Aug 2020 17:17' | System | 23 Aug 2020 22:17:53 |



FDA-CBER-2022-1614-1684485

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684486

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684487

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 5' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684488

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:33:38', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0e992768-0fd9-4fc0-a103-3d8a3f77d7ac' | System | 24 Aug 2020 20:34:38 |
| User entered 'Any use of prescription pain reliever or prevents daily activity (3)' | System | 24 Aug 2020 20:34:38 |



FDA-CBER-2022-1614-1684489

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:33:44', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0e992768-0fd9-4fc0-a103-3d8a3f77d7ac' | System | 24 Aug 2020 20:34:38 |
| User entered 'Some interference with activity (2)' | System | 24 Aug 2020 20:34:38 |



FDA-CBER-2022-1614-1684490

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:33:51', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0e992768-0fd9-4fc0-a103-3d8a3f77d7ac' | System | 24 Aug 2020 20:34:38 |
| User entered 'Some interference with activity (2)' | System | 24 Aug 2020 20:34:38 |



FDA-CBER-2022-1614-1684491

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:33:55', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0e992768-0fd9-4fc0-a103-3d8a3f77d7ac' | System | 24 Aug 2020 20:34:38 |
| User entered 'None (0)' | System | 24 Aug 2020 20:34:38 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:33:58', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0e992768-0fd9-4fc0-a103-3d8a3f77d7ac' | System | 24 Aug 2020 20:34:38 |
| User entered 'None (0)' | System | 24 Aug 2020 20:34:38 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:34:01', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0e992768-0fd9-4fc0-a103-3d8a3f77d7ac' | System | 24 Aug 2020 20:34:38 |
| User entered 'None (0)' | System | 24 Aug 2020 20:34:38 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:34:33', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0e992768-0fd9-4fc0-a103-3d8a3f77d7ac' | System | 24 Aug 2020 20:34:38 |
| User entered 'No (N)' | System | 24 Aug 2020 20:34:38 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-24T15:34:36', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '0e992768-0fd9-4fc0-a103-3d8a3f77d7ac' | System | 24 Aug 2020 20:34:38 |
| User entered '24 Aug 2020 15:34' | System | 24 Aug 2020 20:34:38 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684497

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684498

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 6' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684499

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:49:38', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '7336a005-2a1e-4692-9866-da904d4f108c' | System | 25 Aug 2020 21:50:14 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 25 Aug 2020 21:50:14 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:49:43', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '7336a005-2a1e-4692-9866-da904d4f108c' | System | 25 Aug 2020 21:50:14 |
| User entered 'Some interference with activity (2)' | System | 25 Aug 2020 21:50:14 |



FDA-CBER-2022-1614-1684501

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:49:50', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '7336a005-2a1e-4692-9866-da904d4f108c' | System | 25 Aug 2020 21:50:14 |
| User entered 'None (0)' | System | 25 Aug 2020 21:50:14 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:49:55', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '7336a005-2a1e-4692-9866-da904d4f108c' | System | 25 Aug 2020 21:50:14 |
| User entered 'None (0)' | System | 25 Aug 2020 21:50:14 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:49:58', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '7336a005-2a1e-4692-9866-da904d4f108c' | System | 25 Aug 2020 21:50:14 |
| User entered 'None (0)' | System | 25 Aug 2020 21:50:14 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:50:01', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '7336a005-2a1e-4692-9866-da904d4f108c' | System | 25 Aug 2020 21:50:14 |
| User entered 'None (0)' | System | 25 Aug 2020 21:50:14 |



FDA-CBER-2022-1614-1684505

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:50:07', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '7336a005-2a1e-4692-9866-da904d4f108c' | System | 25 Aug 2020 21:50:14 |
| User entered 'No (N)' | System | 25 Aug 2020 21:50:14 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-25T16:50:11', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '7336a005-2a1e-4692-9866-da904d4f108c' | System | 25 Aug 2020 21:50:14 |
| User entered '25 Aug 2020 16:50' | System | 25 Aug 2020 21:50:14 |



FDA-CBER-2022-1614-1684507

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684508

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684509

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 7' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684510

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:17:27', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b7445746-4db3-4378-8382-2609870e5b17' | System | 26 Aug 2020 22:18:45 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 26 Aug 2020 22:18:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:17:32', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b7445746-4db3-4378-8382-2609870e5b17' | System | 26 Aug 2020 22:18:45 |
| User entered 'Significant; prevents daily activity (3)' | System | 26 Aug 2020 22:18:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:17:37', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b7445746-4db3-4378-8382-2609870e5b17' | System | 26 Aug 2020 22:18:45 |
| User entered 'Significant; prevents daily activity (3)' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684513

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:17:45', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b7445746-4db3-4378-8382-2609870e5b17' | System | 26 Aug 2020 22:18:45 |
| User entered 'No interference with activity (1)' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684514

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:17:59', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b7445746-4db3-4378-8382-2609870e5b17' | System | 26 Aug 2020 22:18:45 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)' | System | 26 Aug 2020 22:18:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:18:08', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b7445746-4db3-4378-8382-2609870e5b17' | System | 26 Aug 2020 22:18:45 |
| User entered 'None (0)' | System | 26 Aug 2020 22:18:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:18:35', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b7445746-4db3-4378-8382-2609870e5b17' | System | 26 Aug 2020 22:18:45 |
| User entered 'No (N)' | System | 26 Aug 2020 22:18:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-26T17:18:43', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b7445746-4db3-4378-8382-2609870e5b17' | System | 26 Aug 2020 22:18:45 |
| User entered '26 Aug 2020 17:18' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684518

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684519

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684520

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 25 Aug 2020 21:50:14 |
| User entered 'Day 8' | System | 25 Aug 2020 21:50:14 |



FDA-CBER-2022-1614-1684521

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:03:09', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '9428f7a4-bffa-4219-b534-f0502565128a' | System | 28 Aug 2020 00:03:22 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity (2)' | System | 28 Aug 2020 00:03:22 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:03:15', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '9428f7a4-bffa-4219-b534-f0502565128a' | System | 28 Aug 2020 00:03:22 |
| User entered '27 Aug 2020 19:03' | System | 28 Aug 2020 00:03:22 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '27 Aug 2020 12:00' | System | 25 Aug 2020 21:50:14 |



FDA-CBER-2022-1614-1684524

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 11:59' | System | 25 Aug 2020 21:50:14 |



FDA-CBER-2022-1614-1684525

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 26 Aug 2020 22:18:45 |
| User entered 'Day 9' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684526

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684527

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684528

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684529

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684530

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 28 Aug 2020 00:03:22 |
| User entered 'Day 10' | System | 28 Aug 2020 00:03:22 |



FDA-CBER-2022-1614-1684531

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**

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

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684532

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684533

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 12:00' | System | 28 Aug 2020 00:03:22 |



FDA-CBER-2022-1614-1684534

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Headache_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '30 Aug 2020 11:59' | System | 28 Aug 2020 00:03:22 |



FDA-CBER-2022-1614-1684535

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 25 Aug 2020 21:50:14 |
| User entered 'Day 8' | System | 25 Aug 2020 21:50:14 |



FDA-CBER-2022-1614-1684536

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:03:21', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd9dd891c-2381-4704-a3b6-0e006023a0ea' | System | 28 Aug 2020 00:03:33 |
| User entered 'Significant; prevents daily activity (3)' | System | 28 Aug 2020 00:03:33 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:03:27', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd9dd891c-2381-4704-a3b6-0e006023a0ea' | System | 28 Aug 2020 00:03:33 |
| User entered '27 Aug 2020 19:03' | System | 28 Aug 2020 00:03:33 |



FDA-CBER-2022-1614-1684538

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '27 Aug 2020 12:00' | System | 25 Aug 2020 21:50:14 |



FDA-CBER-2022-1614-1684539

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 11:59' | System | 25 Aug 2020 21:50:14 |



FDA-CBER-2022-1614-1684540

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 26 Aug 2020 22:18:45 |
| User entered 'Day 9' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684541

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**

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

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684542

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684544

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684545

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 28 Aug 2020 00:03:33 |
| User entered 'Day 10' | System | 28 Aug 2020 00:03:33 |



FDA-CBER-2022-1614-1684546

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**

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

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684547

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684548

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 12:00' | System | 28 Aug 2020 00:03:33 |



FDA-CBER-2022-1614-1684549

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Fatigue_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '30 Aug 2020 11:59' | System | 28 Aug 2020 00:03:33 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 26 Aug 2020 22:18:45 |
| User entered 'Day 8' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684551

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**

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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:03:33', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b78f7864-0b28-4d63-8605-4facb380e055' | System | 28 Aug 2020 00:03:40 |
| User entered 'Some interference with activity (2)' | System | 28 Aug 2020 00:03:40 |



FDA-CBER-2022-1614-1684552

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:03:39', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b78f7864-0b28-4d63-8605-4facb380e055' | System | 28 Aug 2020 00:03:40 |
| User entered '27 Aug 2020 19:03' | System | 28 Aug 2020 00:03:40 |



FDA-CBER-2022-1614-1684553

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 22:18:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684555

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 26 Aug 2020 22:18:45 |
| User entered 'Day 9' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684556

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**

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) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684557

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684558

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 22:18:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 22:18:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 28 Aug 2020 00:03:40 |
| User entered 'Day 10' | System | 28 Aug 2020 00:03:40 |



FDA-CBER-2022-1614-1684561

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**

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) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684562

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 12:00' | System | 28 Aug 2020 00:03:40 |



FDA-CBER-2022-1614-1684564

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: MuscleAche_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '30 Aug 2020 11:59' | System | 28 Aug 2020 00:03:40 |



FDA-CBER-2022-1614-1684565

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 26 Aug 2020 22:18:45 |
| User entered 'Day 8' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684566

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:03:50', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '4b062fd8-4889-45d1-a4a4-40a19333381c' | System | 28 Aug 2020 00:03:59 |
| User entered 'No interference with activity (1)' | System | 28 Aug 2020 00:03:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:03:54', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '4b062fd8-4889-45d1-a4a4-40a19333381c' | System | 28 Aug 2020 00:03:59 |
| User entered '27 Aug 2020 19:03' | System | 28 Aug 2020 00:03:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684569

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684570

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 26 Aug 2020 22:18:45 |
| User entered 'Day 9' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684571

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**

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) | 05 Mar 2021 00:06:09 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684573

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684574

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684575

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 28 Aug 2020 00:03:59 |
| User entered 'Day 10' | System | 28 Aug 2020 00:03:59 |



FDA-CBER-2022-1614-1684576

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**

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) | 05 Mar 2021 00:06:09 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684578

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 12:00' | System | 28 Aug 2020 00:03:59 |



FDA-CBER-2022-1614-1684579

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: JointsAche_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '30 Aug 2020 11:59' | System | 28 Aug 2020 00:03:59 |



FDA-CBER-2022-1614-1684580

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 26 Aug 2020 22:18:45 |
| User entered 'Day 8' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684581

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**

Select one response below to indicate the level of your **NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:04:02', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '9029e2ba-7558-4ee3-9e29-8db6d24af2bc' | System | 28 Aug 2020 00:04:10 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)' | System | 28 Aug 2020 00:04:10 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:04:07', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '9029e2ba-7558-4ee3-9e29-8db6d24af2bc' | System | 28 Aug 2020 00:04:10 |
| User entered '27 Aug 2020 19:04' | System | 28 Aug 2020 00:04:10 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684584

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684585

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 26 Aug 2020 22:18:45 |
| User entered 'Day 9' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684586

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**

Select one response below to indicate the level of your **NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684587

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684588

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 22:18:45 |



FDA-CBER-2022-1614-1684589

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 22:18:45 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 28 Aug 2020 00:04:10 |
| User entered 'Day 10' | System | 28 Aug 2020 00:04:10 |



FDA-CBER-2022-1614-1684591

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**

Select one response below to indicate the level of your **NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684592

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 12:00' | System | 28 Aug 2020 00:04:10 |



FDA-CBER-2022-1614-1684594

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Nausea_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '30 Aug 2020 11:59' | System | 28 Aug 2020 00:04:10 |



FDA-CBER-2022-1614-1684595

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 25 Aug 2020 21:48:58 |
| User entered 'Day 8' | System | 25 Aug 2020 21:48:58 |



FDA-CBER-2022-1614-1684596

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:04:16', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '728eb75d-9e40-44e7-b85e-14d9beab9deb' | System | 28 Aug 2020 00:04:22 |
| User entered 'Yes (Y)' | System | 28 Aug 2020 00:04:22 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-08-27T19:04:20', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '728eb75d-9e40-44e7-b85e-14d9beab9deb' | System | 28 Aug 2020 00:04:22 |
| User entered '27 Aug 2020 19:04' | System | 28 Aug 2020 00:04:22 |



FDA-CBER-2022-1614-1684598

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '27 Aug 2020 12:00' | System | 25 Aug 2020 21:48:58 |



FDA-CBER-2022-1614-1684599

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(8)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 11:59' | System | 25 Aug 2020 21:48:58 |



FDA-CBER-2022-1614-1684600

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 26 Aug 2020 22:16:12 |
| User entered 'Day 9' | System | 26 Aug 2020 22:16:12 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
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) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684602

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684603

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 22:16:12 |



FDA-CBER-2022-1614-1684604

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(9)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 22:16:12 |



FDA-CBER-2022-1614-1684605

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 28 Aug 2020 00:02:59 |
| User entered 'Day 10' | System | 28 Aug 2020 00:02:59 |



FDA-CBER-2022-1614-1684606

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
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) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684607

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |



FDA-CBER-2022-1614-1684608

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '29 Aug 2020 12:00' | System | 28 Aug 2020 00:02:59 |

**US3292241**
**Folder: Diary Dose 1 (1)**
**Form: Medical Attention_Day(10)**
**Generated On: 11 Aug 2021 22:21:07**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| User entered '30 Aug 2020 11:59' | System | 28 Aug 2020 00:02:59 |

**US3292241**
**Folder: Safety Call Day 8 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:09 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'No (N)' | Gerardo Pena (b) (4) (b) (4) | 27 Jan 2021 23:19:22 |



FDA-CBER-2022-1614-1684611

**US3292241**
**Folder: Safety Call Day 8 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:09 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 27 Jan 2021 23:19:22 |

**US3292241**
**Folder: Safety Call Day 8 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:09 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 27 Jan 2021 23:19:22 |



FDA-CBER-2022-1614-1684613

**US3292241**
**Folder: Safety Call Day 8 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:09 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Subject was in the convalescent period.' reason for change: Data Entry Error | Gerardo Pena (b) (4) (b) (4) | 28 Jan 2021 15:46:06 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 27 Jan 2021 23:19:22 |



FDA-CBER-2022-1614-1684614

**US3292241**
**Folder: Safety Call Day 8 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:13 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 26 Sep 2020 16:40:53 |



FDA-CBER-2022-1614-1684615

**US3292241**
**Folder: Safety Call Day 8 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 26 Sep 2020 16:40:53 |



FDA-CBER-2022-1614-1684616

**US3292241**
**Folder: Safety Call Day 15 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:18 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'No (N)' | Gerardo Pena (b) (4) (b) (4) | 27 Jan 2021 23:19:28 |

**US3292241**
**Folder: Safety Call Day 15 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:18 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 27 Jan 2021 23:19:28 |



FDA-CBER-2022-1614-1684618

**US3292241**
**Folder: Safety Call Day 15 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:18 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 27 Jan 2021 23:19:28 |

**US3292241**
**Folder: Safety Call Day 15 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:18 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Subject was in the convalescent period.' reason for change: Data Entry Error | Gerardo Pena (b) (4) (b) (4) | 28 Jan 2021 15:46:14 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 27 Jan 2021 23:19:28 |

**US3292241**
**Folder: Safety Call Day 15 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:21 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 26 Sep 2020 16:41:02 |



FDA-CBER-2022-1614-1684621

**US3292241**
**Folder: Safety Call Day 15 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 26 Sep 2020 16:41:02 |

**US3292241**
**Folder: Safety Call Day 22 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:25 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'No (N)' | Gerardo Pena (b) (4) (b) (4) | 27 Jan 2021 23:19:34 |

**US3292241**
**Folder: Safety Call Day 22 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:25 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 27 Jan 2021 23:19:34 |

**US3292241**
**Folder: Safety Call Day 22 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:25 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 27 Jan 2021 23:19:34 |

**US3292241**
**Folder: Safety Call Day 22 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:25 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Subject was in the convalescent period.' reason for change: Data Entry Error | Gerardo Pena (b) (4) (b) (4) | 28 Jan 2021 15:46:21 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 27 Jan 2021 23:19:34 |

**US3292241**
**Folder: Safety Call Day 22 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:08:29 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 26 Sep 2020 16:41:12 |



FDA-CBER-2022-1614-1684627

**US3292241**
**Folder: Safety Call Day 22 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 26 Sep 2020 16:41:12 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was this visit performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:14:52 |
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:13:19 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:14:52 |
| User entered '24 Sep 2020' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:13:19 |



FDA-CBER-2022-1614-1684630

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:14:52 |
| User entered 'Clinic (Clinic)' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:13:19 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Folder OID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'VISIT2' | System | 04 Nov 2020 22:13:19 |



FDA-CBER-2022-1614-1684632

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Timepoint

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684633

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered '24 Sep 2020' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684635

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered '12:05' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered '24 Sep 2020 12:05' | System | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684637

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered '37.6' C | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered 'Oral (Oral)' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684640

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered '85' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684641

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'bpm' | System | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684642

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered '16' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'breaths/min' | System | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684644

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered '142' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'mmHg' | System | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684646

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered '98' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684647

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'mmHg' | System | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684648

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Timepoint

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684649

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 24 Nov 2020 09:47:23 |
| Query 'Data is required. Please complete.' answered with 'post-dose vitals were not done, subject opted out of receiving second dose' (Site from System). | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:53 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 04 Nov 2020 22:15:04 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684651

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered empty. | System | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684653

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684654

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684656

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684657

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered empty. | System | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684658

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684659

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered empty. | System | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684660

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684661

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered empty. | System | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684662

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:16:18 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:15:04 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered empty. | System | 04 Nov 2020 22:15:04 |



FDA-CBER-2022-1614-1684664

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Physical Examination**
**Generated On: 11 Aug 2021 22:21:07**
Was the physical examination performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:17:14 |
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:16:18 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Physical Examination**
**Generated On: 11 Aug 2021 22:21:07**
Date of examination *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:17:14 |
| User entered '24 Sep 2020' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:16:18 |



FDA-CBER-2022-1614-1684666

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
Was study treatment given?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:19:18 |
| User entered 'No (N)' | Nathan Cortez (b) (4) | 26 Sep 2020 16:42:49 |



FDA-CBER-2022-1614-1684667

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
If No, reason not given

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Feb 2021 19:47:08 |
| User closed query 'Please confirm reason for discontinuation. If subject withdrew due to AE, please specify in source.' (Site from CRA). | | 11 Feb 2021 19:47:07 |
| Query 'Please confirm reason for discontinuation. If subject withdrew due to AE, please specify in source.' answered with 'updated with reason specifications' (Site from CRA). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:51:39 |
| User opened query 'Please confirm reason for discontinuation. If subject withdrew due to AE, please specify in source.' (Site from CRA). | (b) (4), (b) (6) | 15 Jan 2021 13:19:08 |
| User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)' | Nathan Cortez (b) (4) | 26 Sep 2020 16:42:49 |



FDA-CBER-2022-1614-1684668

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:47:08 |
| DataPoint Verified. | | 13 Apr 2021 17:16:04 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Un-verified. | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:51:20 |
| User entered 'Subject developed lymphadenitis therefore withdrew from study' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:51:20 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:21:35 |
| User entered empty. | Nathan Cortez (b) (4) | 26 Sep 2020 16:42:49 |



FDA-CBER-2022-1614-1684669

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
What was the study treatment?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered empty. | System | 26 Sep 2020 16:42:49 |



FDA-CBER-2022-1614-1684670

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
What was the treatment date? *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:21:37 |
| User entered empty. | Nathan Cortez (b) (4) | 26 Sep 2020 16:42:49 |



FDA-CBER-2022-1614-1684671

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
What was the treatment time? *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:21:39 |
| User entered empty. | Nathan Cortez (b) (4) | 26 Sep 2020 16:42:49 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
Treatment Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered empty. | System | 26 Sep 2020 16:42:49 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:21:40 |
| User entered empty. | Nathan Cortez (b) (4) | 26 Sep 2020 16:42:49 |



FDA-CBER-2022-1614-1684674

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| DataPoint Verified. | | 15 Jan 2021 13:21:41 |
| User entered empty. | | 26 Sep 2020 16:42:49 |



FDA-CBER-2022-1614-1684675

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 11 Aug 2021 22:21:07**
What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered empty. | System | 26 Sep 2020 16:42:49 |



FDA-CBER-2022-1614-1684676

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:22:26 |
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:16:50 |



FDA-CBER-2022-1614-1684677

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Collection date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:22:26 |
| User entered '24 Sep 2020' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:16:50 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Collection time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:22:26 |
| User entered '12:28' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:16:50 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered '24 Sep 2020 12:28' | System | 04 Nov 2020 22:16:50 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab**
**Generated On: 11 Aug 2021 22:21:07**
Collection date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:22:32 |
| User entered '24 Sep 2020' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:17:06 |



FDA-CBER-2022-1614-1684681

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 11 Aug 2021 22:21:07**
Lab Test

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:17:06 |



FDA-CBER-2022-1614-1684682

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 11 Aug 2021 22:21:07**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:22:32 |
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:17:06 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 11 Aug 2021 22:21:07**
Collection time *(00:00 - 23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:22:32 |
| User entered '13:02' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:17:06 |



FDA-CBER-2022-1614-1684684

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 11 Aug 2021 22:21:07**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered '24 Sep 2020 13:02' | System | 04 Nov 2020 22:17:06 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 11 Aug 2021 22:21:07**
Lab Test

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:17:06 |



FDA-CBER-2022-1614-1684686

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 11 Aug 2021 22:21:07**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:22:32 |
| User entered 'No (N)' | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:17:06 |



FDA-CBER-2022-1614-1684687

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 11 Aug 2021 22:21:07**
Collection time *(00:00 - 23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:22:32 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 22:17:06 |

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 11 Aug 2021 22:21:07**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered empty. | System | 04 Nov 2020 22:17:06 |



FDA-CBER-2022-1614-1684689

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:22:36 |
| User entered 'Yes (Y)' | | 01 Oct 2020 20:02:34 |



FDA-CBER-2022-1614-1684690

**US3292241**
**Folder: Visit 2 Day 29 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered '1' | System | 01 Oct 2020 20:02:34 |



FDA-CBER-2022-1614-1684691

**US3292241**
**Folder: Safety Call Day 36 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:35:44 |
| User entered 'Yes (Y)' | | 01 Oct 2020 20:03:44 |



FDA-CBER-2022-1614-1684692

**US3292241**
**Folder: Safety Call Day 36 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:35:44 |
| User entered '1 Oct 2020' | | 01 Oct 2020 20:03:44 |

**US3292241**
**Folder: Safety Call Day 36 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:35:44 |
| User entered 'Contact Made (CONTACT MADE)' | | 01 Oct 2020 20:03:44 |

**US3292241**
**Folder: Safety Call Day 36 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:35:44 |
| User entered empty. | | 01 Oct 2020 20:03:44 |



FDA-CBER-2022-1614-1684695

**US3292241**
**Folder: Safety Call Day 36 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:36:35 |
| User entered 'Yes (Y)' | | 01 Oct 2020 20:04:19 |



FDA-CBER-2022-1614-1684696

**US3292241**
**Folder: Safety Call Day 36 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 01 Oct 2020 20:04:19 |



FDA-CBER-2022-1614-1684697

**US3292241**
**Folder: Safety Call Day 43 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:38:29 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 08 Oct 2020 16:13:32 |

**US3292241**
**Folder: Safety Call Day 43 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:38:29 |
| User entered '8 Oct 2020' | Kristy Trevino (b) (4) (b) (4) | 08 Oct 2020 16:13:32 |



FDA-CBER-2022-1614-1684699

**US3292241**
**Folder: Safety Call Day 43 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:38:29 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) (b) (4) | 08 Oct 2020 16:13:32 |



FDA-CBER-2022-1614-1684700

**US3292241**
**Folder: Safety Call Day 43 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:38:29 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 08 Oct 2020 16:13:32 |



FDA-CBER-2022-1614-1684701

**US3292241**
**Folder: Safety Call Day 43 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:38:38 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 08 Oct 2020 16:13:39 |

**US3292241**
**Folder: Safety Call Day 43 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 08 Oct 2020 16:13:39 |



FDA-CBER-2022-1614-1684703

**US3292241**
**Folder: Safety Call Day 50 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:39:40 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 15 Oct 2020 21:05:38 |

**US3292241**
**Folder: Safety Call Day 50 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:39:40 |
| User entered '15 Oct 2020' | Kristy Trevino (b) (4) (b) (4) | 15 Oct 2020 21:05:38 |

**US3292241**
**Folder: Safety Call Day 50 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:39:40 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) (b) (4) | 15 Oct 2020 21:05:38 |

**US3292241**
**Folder: Safety Call Day 50 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:39:40 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 15 Oct 2020 21:05:38 |



FDA-CBER-2022-1614-1684707

**US3292241**
**Folder: Safety Call Day 50 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:39:46 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 15 Oct 2020 21:05:43 |



FDA-CBER-2022-1614-1684708

**US3292241**
**Folder: Safety Call Day 50 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 15 Oct 2020 21:05:43 |



FDA-CBER-2022-1614-1684709

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was this visit performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:04 |
| User entered 'Yes (Y)' | | 27 Oct 2020 18:20:37 |



FDA-CBER-2022-1614-1684710

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:04 |
| User entered '27 Oct 2020' | | 27 Oct 2020 18:20:37 |

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:04 |
| User entered 'Clinic (Clinic)' | | 27 Oct 2020 18:20:37 |



FDA-CBER-2022-1614-1684712

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Folder OID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'VISIT3' | System | 27 Oct 2020 18:20:37 |



FDA-CBER-2022-1614-1684713

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:36 |
| User entered 'Yes (Y)' | | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684714

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:36 |
| User entered '27 Oct 2020' | | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684715

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:36 |
| User entered '11:09' | | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684716

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered '27 Oct 2020 11:09' | System | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684717

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:36 |
| User entered '37.3' C | | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684718

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:36 |
| User entered 'Oral (Oral)' | | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684719

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:36 |
| User entered empty. | | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684720

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:36 |
| User entered '86' | | 27 Oct 2020 18:21:31 |

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'bpm' | System | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684722

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:36 |
| User entered '16' | | 27 Oct 2020 18:21:31 |

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'breaths/min' | System | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684724

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:36 |
| User entered '129' | | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684725

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'mmHg' | System | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684726

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:28:36 |
| User entered '91' | | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684727

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered 'mmHg' | System | 27 Oct 2020 18:21:31 |



FDA-CBER-2022-1614-1684728

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Height (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |



FDA-CBER-2022-1614-1684729

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Weight (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |



FDA-CBER-2022-1614-1684730

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Physical Examination**
**Generated On: 11 Aug 2021 22:21:07**
Was the physical examination performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:29:50 |
| User entered 'No (N)' | | 27 Oct 2020 18:21:35 |



FDA-CBER-2022-1614-1684731

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Physical Examination**
**Generated On: 11 Aug 2021 22:21:07**
Date of examination *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:29:50 |
| User entered empty. | | 27 Oct 2020 18:21:35 |



FDA-CBER-2022-1614-1684732

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:30:03 |
| User entered 'Yes (Y)' | | 27 Oct 2020 18:21:51 |



FDA-CBER-2022-1614-1684733

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Collection date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:30:03 |
| User entered '27 Oct 2020' | | 27 Oct 2020 18:21:51 |



FDA-CBER-2022-1614-1684734

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Collection time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:30:03 |
| User entered '11:39' | | 27 Oct 2020 18:21:51 |

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered '27 Oct 2020 11:39' | System | 27 Oct 2020 18:21:51 |



FDA-CBER-2022-1614-1684736

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:30:59 |
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 27 Oct 2020 19:11:38 |



FDA-CBER-2022-1614-1684737

**US3292241**
**Folder: Visit 3 Day 57 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:47:08 |
| User entered '1' | System | 27 Oct 2020 19:11:38 |



FDA-CBER-2022-1614-1684738

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 64' | System | 20 Aug 2020 17:18:12 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Have you been exposed to someone with 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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Please 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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Fever (Temperature ≥ 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684745

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684746

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684747

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684748

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684749

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Muscle aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Body aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684751

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684752

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
New loss of taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
New loss of smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Sore throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684755

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684756

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Runny nose

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684757

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684758

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684759

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Please 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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Please 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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered '20 Oct 2020 00:01' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684765

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered '24 Oct 2020 23:59' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684766

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 71' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684767

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-10-28T13:16:30', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '006ec293-015a-448b-b19c-2eeee066063d' | System | 28 Oct 2020 18:17:33 |
| User entered 'No (N)' | System | 28 Oct 2020 18:17:33 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Have you been exposed to someone with 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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-10-28T13:16:58', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '006ec293-015a-448b-b19c-2eeee066063d' | System | 28 Oct 2020 18:17:33 |
| User entered 'No (N)' | System | 28 Oct 2020 18:17:33 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-10-28T13:17:30', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '006ec293-015a-448b-b19c-2eeee066063d' | System | 28 Oct 2020 18:17:33 |
| User entered '28 Oct 2020 13:17:30' | System | 28 Oct 2020 18:17:33 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered '27 Oct 2020 00:01' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684771

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered '31 Oct 2020 23:59' | System | 20 Aug 2020 17:18:12 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 78' | System | 20 Aug 2020 17:18:12 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-11-04T14:02:47', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd6c50970-5bd3-4209-b805-a4d3e7e6547e' | System | 04 Nov 2020 20:03:33 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 20:03:33 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Have you been exposed to someone with 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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-11-04T14:02:52', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd6c50970-5bd3-4209-b805-a4d3e7e6547e' | System | 04 Nov 2020 20:03:33 |
| User entered 'No (N)' | System | 04 Nov 2020 20:03:33 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-11-04T14:02:57', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd6c50970-5bd3-4209-b805-a4d3e7e6547e' | System | 04 Nov 2020 20:03:33 |
| User entered 'No (N)' | System | 04 Nov 2020 20:03:33 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-11-04T14:03:08', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd6c50970-5bd3-4209-b805-a4d3e7e6547e' | System | 04 Nov 2020 20:03:33 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 20:03:33 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Please 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) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-11-04T14:03:17', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd6c50970-5bd3-4209-b805-a4d3e7e6547e' | System | 04 Nov 2020 20:03:33 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 04 Nov 2020 20:03:33 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-11-04T14:03:22', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'd6c50970-5bd3-4209-b805-a4d3e7e6547e' | System | 04 Nov 2020 20:03:33 |
| User entered '04 Nov 2020 14:03:22' | System | 04 Nov 2020 20:03:33 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered '03 Nov 2020 00:01' | System | 20 Aug 2020 17:18:12 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:09 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered '07 Nov 2020 23:59' | System | 20 Aug 2020 17:18:12 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered 'Day 92' | System | 20 Aug 2020 17:18:12 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Have you been exposed to someone with 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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Please 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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Fever (Temperature ≥ 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684788

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684790

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684791

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Muscle aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Body aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684795

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
New loss of taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684796

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
New loss of smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Sore throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684798

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Runny nose

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684801

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Please 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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Please 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) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered '17 Nov 2020 00:01' | System | 20 Aug 2020 17:18:12 |



FDA-CBER-2022-1614-1684808

**US3292241**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:39:31 |
| Data entry locked. | System | 20 Aug 2020 17:18:12 |
| User entered '21 Nov 2020 23:59' | System | 20 Aug 2020 17:18:12 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 23:39:31 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-11-24T14:23:48', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '68dfca0a-aa63-47a9-b791-3fef95850e47' | System | 24 Nov 2020 20:24:04 |
| User entered 'No (N)' | System | 24 Nov 2020 20:24:04 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Have you been exposed to someone with 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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-11-24T14:23:54', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '68dfca0a-aa63-47a9-b791-3fef95850e47' | System | 24 Nov 2020 20:24:04 |
| User entered 'No (N)' | System | 24 Nov 2020 20:24:04 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-11-24T14:24:02', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '68dfca0a-aa63-47a9-b791-3fef95850e47' | System | 24 Nov 2020 20:24:04 |
| User entered '24 Nov 2020 14:24:02' | System | 24 Nov 2020 20:24:04 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684814

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684815

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684816

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM). | | 07 Apr 2021 06:57:05 |
| Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'NO AEs to note. This was due to patient's ongoing gastric issues already noted in MedHx, as per progress note. ' (Site from DM). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:19:24 |
| User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM). | (b) (4), (b) (6) | 28 Feb 2021 06:22:27 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-02T10:29:47', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '85e02044-a4bf-4f30-8493-4658877c7d1f' | System | 02 Dec 2020 16:30:30 |
| User entered 'Yes (Y)' | System | 02 Dec 2020 16:30:30 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Have you been exposed to someone with 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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-02T10:29:53', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '85e02044-a4bf-4f30-8493-4658877c7d1f' | System | 02 Dec 2020 16:30:30 |
| User entered 'No (N)' | System | 02 Dec 2020 16:30:30 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-02T10:29:59', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '85e02044-a4bf-4f30-8493-4658877c7d1f' | System | 02 Dec 2020 16:30:30 |
| User entered 'No (N)' | System | 02 Dec 2020 16:30:30 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-02T10:30:05', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '85e02044-a4bf-4f30-8493-4658877c7d1f' | System | 02 Dec 2020 16:30:30 |
| User entered 'Yes (Y)' | System | 02 Dec 2020 16:30:30 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Please 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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-02T10:30:13', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '85e02044-a4bf-4f30-8493-4658877c7d1f' | System | 02 Dec 2020 16:30:30 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 02 Dec 2020 16:30:30 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-02T10:30:18', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '85e02044-a4bf-4f30-8493-4658877c7d1f' | System | 02 Dec 2020 16:30:30 |
| User entered '02 Dec 2020 10:30:18' | System | 02 Dec 2020 16:30:30 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684823

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 19 Nov 2020 23:39:31 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684825

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Have you been exposed to someone with 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) | 26 Apr 2021 18:46:52 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Please 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) | 26 Apr 2021 18:46:52 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Fever (Temperature ≥ 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684831

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684835

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Muscle aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684836

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Body aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
New loss of taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684839

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
New loss of smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684840

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Sore throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684841

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684842

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Runny nose

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684843

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684844

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684845

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684846

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Please 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) | 26 Apr 2021 18:46:52 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1684848

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Please 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) | 26 Apr 2021 18:46:52 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684851

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684852

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684853

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-12T10:03:56', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'abc53a0f-e7d5-49c3-838c-b460d052f56a' | System | 12 Dec 2020 16:04:07 |
| User entered 'No (N)' | System | 12 Dec 2020 16:04:07 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Have you been exposed to someone with 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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-12T10:03:47', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'abc53a0f-e7d5-49c3-838c-b460d052f56a' | System | 12 Dec 2020 16:04:07 |
| User entered 'No (N)' | System | 12 Dec 2020 16:04:07 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-12T10:04:05', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'abc53a0f-e7d5-49c3-838c-b460d052f56a' | System | 12 Dec 2020 16:04:07 |
| User entered '12 Dec 2020 10:04:05' | System | 12 Dec 2020 16:04:07 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684857

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684858

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684859

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-19T08:19:03', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '7306831c-efa9-42f5-a04c-4658fcd4aa9d' | System | 19 Dec 2020 14:19:35 |
| User entered 'No (N)' | System | 19 Dec 2020 14:19:35 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Have you been exposed to someone with 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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-19T08:19:07', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '7306831c-efa9-42f5-a04c-4658fcd4aa9d' | System | 19 Dec 2020 14:19:35 |
| User entered 'No (N)' | System | 19 Dec 2020 14:19:35 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-19T08:19:33', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: '7306831c-efa9-42f5-a04c-4658fcd4aa9d' | System | 19 Dec 2020 14:19:35 |
| User entered '19 Dec 2020 08:19:33' | System | 19 Dec 2020 14:19:35 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684863

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684864

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684865

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-28T09:40:47', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'e0f1f828-82eb-4214-aace-b6f3be7802f5' | System | 28 Dec 2020 15:41:16 |
| User entered 'Yes (Y)' | System | 28 Dec 2020 15:41:16 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Have you been exposed to someone with 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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-28T09:40:51', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'e0f1f828-82eb-4214-aace-b6f3be7802f5' | System | 28 Dec 2020 15:41:16 |
| User entered 'No (N)' | System | 28 Dec 2020 15:41:16 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-28T09:40:55', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'e0f1f828-82eb-4214-aace-b6f3be7802f5' | System | 28 Dec 2020 15:41:16 |
| User entered 'No (N)' | System | 28 Dec 2020 15:41:16 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-28T09:41:00', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'e0f1f828-82eb-4214-aace-b6f3be7802f5' | System | 28 Dec 2020 15:41:16 |
| User entered 'No (N)' | System | 28 Dec 2020 15:41:16 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2020-12-28T09:41:10', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'e0f1f828-82eb-4214-aace-b6f3be7802f5' | System | 28 Dec 2020 15:41:16 |
| User entered '28 Dec 2020 09:41:10' | System | 28 Dec 2020 15:41:16 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684871

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684872

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 23:39:31 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2021-01-11T09:45:52', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b0ada5f9-0775-44e9-a680-99081a7c3e5f' | System | 11 Jan 2021 15:46:03 |
| User entered 'No (N)' | System | 11 Jan 2021 15:46:03 |

**US3292241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:21:07**

Have you been exposed to someone with 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) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2021-01-11T09:45:56', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b0ada5f9-0775-44e9-a680-99081a7c3e5f' | System | 11 Jan 2021 15:46:03 |
| User entered 'No (N)' | System | 11 Jan 2021 15:46:03 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0DA7FE0-818A-4F2F-B1B9-48568184735C)', Time: '2021-01-11T09:46:01', User OID: 'PatientReportedOutcome (US3292241)', ODM File OID: 'b0ada5f9-0775-44e9-a680-99081a7c3e5f' | System | 11 Jan 2021 15:46:03 |
| User entered '11 Jan 2021 09:46:01' | System | 11 Jan 2021 15:46:03 |

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684877

**US3292241**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 11 Aug 2021 22:21:07**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:39:31 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 19 Nov 2020 23:39:31 |



FDA-CBER-2022-1614-1684878

**US3292241**
**Folder: Safety Call Day 85 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:45:04 |
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 23 Nov 2020 22:44:28 |

**US3292241**
**Folder: Safety Call Day 85 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:45:04 |
| User entered '19 Nov 2020' | Kevin Martinez (b) (4) (b) (4) | 23 Nov 2020 22:44:28 |

**US3292241**
**Folder: Safety Call Day 85 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:45:04 |
| User entered 'Contact Made (CONTACT MADE)' | Kevin Martinez (b) (4) (b) (4) | 23 Nov 2020 22:44:28 |

**US3292241**
**Folder: Safety Call Day 85 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:45:04 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 23 Nov 2020 22:44:28 |

**US3292241**
**Folder: Safety Call Day 85 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Dec 2020 11:45:11 |
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 23 Nov 2020 22:44:33 |

**US3292241**
**Folder: Safety Call Day 85 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 23 Nov 2020 22:44:33 |



FDA-CBER-2022-1614-1684884

**US3292241**
**Folder: Safety Call Day 119 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:10:10 |
| DataPoint Un-verified. | | 01 Mar 2021 17:55:10 |
| DataPoint Verified. | | 01 Mar 2021 17:54:55 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Dec 2020 15:31:24 |

**US3292241**
**Folder: Safety Call Day 119 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:10:10 |
| DataPoint Un-verified. | | 01 Mar 2021 17:55:12 |
| DataPoint Verified. | | 01 Mar 2021 17:54:55 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered '23 Dec 2020' | (b) (4), (b) (6) | 27 Dec 2020 15:31:24 |



FDA-CBER-2022-1614-1684886

**US3292241**
**Folder: Safety Call Day 119 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:10:10 |
| DataPoint Un-verified. | | 01 Mar 2021 17:55:14 |
| DataPoint Verified. | | 01 Mar 2021 17:54:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 27 Dec 2020 15:31:24 |

**US3292241**
**Folder: Safety Call Day 119 (1)**
**Form: Safety Call**
**Generated On: 11 Aug 2021 22:21:07**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:10:10 |
| DataPoint Un-verified. | | 01 Mar 2021 17:55:15 |
| DataPoint Verified. | | 01 Mar 2021 17:54:55 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | (b) (4), (b) (6) | 27 Dec 2020 15:31:24 |



FDA-CBER-2022-1614-1684888

**US3292241**
**Folder: Safety Call Day 119 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 08 Apr 2021 20:10:14 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Dec 2020 15:31:29 |

**US3292241**
**Folder: Safety Call Day 119 (1)**
**Form: Continuing**
**Generated On: 11 Aug 2021 22:21:07**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 27 Dec 2020 15:31:29 |



FDA-CBER-2022-1614-1684890

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID-19 Contact**
**Generated On: 11 Aug 2021 22:21:07**
Date of Contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:50:43 |
| User entered '27 Aug 2020' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:21:51 |
| User entered '28 Aug 2020' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 19:55:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID-19 Contact**
**Generated On: 11 Aug 2021 22:21:07**
Time of Contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:50:43 |
| User entered '13:05' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:21:51 |
| User entered '14:55' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 19:55:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID-19 Contact**
**Generated On: 11 Aug 2021 22:21:07**
Date and Time of Contact (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '27 Aug 2020 13:05' | System | 06 Nov 2020 17:21:51 |
| User entered '28 Aug 2020 14:55' | System | 28 Aug 2020 19:55:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID-19 Contact**
**Generated On: 11 Aug 2021 22:21:07**
Type of Contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:50:43 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 11 Sep 2020 15:23:17 |
| User entered 'Convalescent Tele-visit (Convalescent Tele-visit)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 19:55:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID-19 Contact**
**Generated On: 11 Aug 2021 22:21:07**
Has the subject reported symptoms of SARS-COV-2?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:50:43 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 19:55:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 2 (Day 2)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:08:17 |
| User entered '28 Aug 2020' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Feb 2021 19:16:28 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:08:23 |
| User entered '98' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Feb 2021 19:16:25 |
| User closed query 'Please confirm value with source' (Site from CRA). | | 11 Feb 2021 19:16:23 |
| Query 'Please confirm value with source' answered with 'updated per source' (Site from CRA). | | 20 Jan 2021 19:41:30 |
| User entered '37.1' C reason for change: Data Entry Error | | 20 Jan 2021 19:41:22 |
| User opened query 'Please confirm value with source' (Site from CRA). | | 15 Jan 2021 14:09:50 |
| User entered '98' F | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:10:02 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:10:05 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:10:06 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:10:09 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:10:21 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:10:25 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:10:29 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:10:31 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:10:34 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:10:36 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |



FDA-CBER-2022-1614-1684911

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:10:39 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:10:41 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Feb 2021 19:16:20 |
| User closed query 'Please confirm with source' (Site from CRA). | | 11 Feb 2021 19:16:19 |
| Query 'Please confirm with source' answered with 'updated per source' (Site from CRA). | | 20 Jan 2021 19:41:51 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | | 20 Jan 2021 19:41:22 |
| User opened query 'Please confirm with source' (Site from CRA). | | 15 Jan 2021 14:11:05 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:11:11 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:11:13 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (1)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:11:15 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:02:14 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 3 (Day 3)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:11:41 |
| User entered '29 Aug 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:11:44 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:11:46 |
| User entered '96' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |



FDA-CBER-2022-1614-1684921

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 01:09:01 |



FDA-CBER-2022-1614-1684922

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:11:47 |
| User entered '35.7' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |



FDA-CBER-2022-1614-1684923

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:11:57 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:11:59 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |



FDA-CBER-2022-1614-1684925

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:01 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |



FDA-CBER-2022-1614-1684926

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:03 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |



FDA-CBER-2022-1614-1684927

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:04 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |



FDA-CBER-2022-1614-1684928

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:06 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |



FDA-CBER-2022-1614-1684929

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:08 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:11 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |



FDA-CBER-2022-1614-1684931

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:20 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:21 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:23 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:15 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:24 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:25 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:27 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |



FDA-CBER-2022-1614-1684938

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (2)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:12:29 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:09:01 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 4 (Day 4)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684940

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:29:36 |
| User entered '30 Aug 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684941

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:30:53 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684942

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:29:38 |
| User entered '98' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684944

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:29:40 |
| User entered '37.1' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:29:47 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:29:49 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:29:50 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684948

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:29:52 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684949

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:29:54 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684950

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:29:56 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684951

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:29:58 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:29:59 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:30:50 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684954

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:30:58 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:30:11 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684956

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:31:11 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:30:28 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684958

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:31:14 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684959

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:31:17 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |



FDA-CBER-2022-1614-1684960

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (3)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Feb 2021 19:16:59 |
| User closed query 'Please confirm with source' (Site from CRA). | | 11 Feb 2021 19:16:49 |
| Query 'Please confirm with source' answered with 'updated per source' (Site from CRA). | | 20 Jan 2021 19:42:59 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | | 20 Jan 2021 19:42:41 |
| User opened query 'Please confirm with source' (Site from CRA). | | 15 Jan 2021 14:30:44 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 01:10:55 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 5 (Day 5)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |



FDA-CBER-2022-1614-1684962

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:31:43 |
| User entered '31 Aug 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:31:45 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |



FDA-CBER-2022-1614-1684964

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:31:47 |
| User entered '98' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |



FDA-CBER-2022-1614-1684965

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:31:48 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 13 Sep 2020 17:47:04 |
| User entered '37.2' C reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:47:04 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 13 Sep 2020 17:46:48 |
| User entered '3702' (non-conformant). | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:07 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:08 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:31:58 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:10 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:11 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:13 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:14 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:00 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:16 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:18 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:02 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:20 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:21 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:23 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:25 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (4)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:27 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:46:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 6 (Day 6)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:47 |
| User entered '1 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:50 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:51 |
| User entered '100' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 17:48:05 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:32:53 |
| User entered '37.6' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:15 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:17 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:19 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:20 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:22 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:23 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:25 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:02 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:26 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |



FDA-CBER-2022-1614-1684998

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:28 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:29 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:31 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:32 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:34 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:36 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (5)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:37 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:48:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 7 (Day 7)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:51 |
| User entered '2 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:55 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:56 |
| User entered '96' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:33:57 |
| User entered '36.8' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:19 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:21 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:22 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |



FDA-CBER-2022-1614-1685014

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:23 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:04 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |



FDA-CBER-2022-1614-1685016

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:25 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:26 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:07 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |



FDA-CBER-2022-1614-1685019

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:28 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |



FDA-CBER-2022-1614-1685020

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:29 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:10 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |



FDA-CBER-2022-1614-1685022

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:31 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:32 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:34 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:35 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (6)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:34:12 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:49:19 |



FDA-CBER-2022-1614-1685027

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 8 (Day 8)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |



FDA-CBER-2022-1614-1685028

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:37:18 |
| User entered '3 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |



FDA-CBER-2022-1614-1685029

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:37:20 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |



FDA-CBER-2022-1614-1685030

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:37:24 |
| User entered '96' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:37:26 |
| User entered '37.6' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:37:28 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:00 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |



FDA-CBER-2022-1614-1685035

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:25 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:27 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:02 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:30 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:31 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:06 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:10 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:33 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:11 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:34 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:36 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:37 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:38 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (7)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:40 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 17:55:29 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 9 (Day 9)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:57 |
| User entered '4 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |



FDA-CBER-2022-1614-1685051

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:39:01 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:38:59 |
| User entered '98' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 18:02:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:39:03 |
| User entered '36.4' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |



FDA-CBER-2022-1614-1685055

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:40:49 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:39:09 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:40:51 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:40:53 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |



FDA-CBER-2022-1614-1685059

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:39:10 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |



FDA-CBER-2022-1614-1685060

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:40:57 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:40:59 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:39:16 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |



FDA-CBER-2022-1614-1685063

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:41:01 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |



FDA-CBER-2022-1614-1685064

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:41:03 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:39:17 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:41:04 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:41:06 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:41:08 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:41:10 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (8)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:41:12 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:02:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 10 (Day 10)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:41:42 |
| User entered '5 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:27 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:41:47 |
| User entered '97' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |



FDA-CBER-2022-1614-1685075

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 18:03:52 |



FDA-CBER-2022-1614-1685076

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:41:49 |
| User entered '36.8' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |



FDA-CBER-2022-1614-1685077

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:25 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:41:56 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:23 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:21 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:20 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:18 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:16 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:02 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |



FDA-CBER-2022-1614-1685085

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:14 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:13 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |



FDA-CBER-2022-1614-1685087

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:11 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:10 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:08 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:07 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:06 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (9)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:04 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:03:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 11 (Day 11)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |



FDA-CBER-2022-1614-1685094

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:48 |
| User entered '6 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |



FDA-CBER-2022-1614-1685095

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:51 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:53 |
| User entered '97' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:55 |
| User entered '37.1' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:57 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:42:59 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:10 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:11 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:13 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:15 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:16 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:06 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |



FDA-CBER-2022-1614-1685107

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:18 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:21 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:22 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |



FDA-CBER-2022-1614-1685110

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:24 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:26 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:28 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:29 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (10)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:31 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:05:07 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 12 (Day 12)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |



FDA-CBER-2022-1614-1685116

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:50 |
| User entered '7 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |



FDA-CBER-2022-1614-1685117

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:52 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:53 |
| User entered '97' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:43:54 |
| User entered '36.8' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:08 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:09 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:10 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:12 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:13 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:20 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:22 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:04 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:24 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:26 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:28 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:31 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:32 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:34 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:36 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (11)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:44:37 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:25:16 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 13 (Day 13)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:18 |
| User entered '8 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |



FDA-CBER-2022-1614-1685139

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:19 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |



FDA-CBER-2022-1614-1685140

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:20 |
| User entered '97' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:24 |
| User entered '36.4' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |



FDA-CBER-2022-1614-1685143

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:38 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:39 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:41 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:42 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:44 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:46 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:47 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:33 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:50 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:52 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:53 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:55 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:57 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |



FDA-CBER-2022-1614-1685156

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:46:59 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:01 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (12)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:03 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:26:31 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 14 (Day 14)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |



FDA-CBER-2022-1614-1685160

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:19 |
| User entered '9 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |



FDA-CBER-2022-1614-1685161

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:21 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |



FDA-CBER-2022-1614-1685162

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:22 |
| User entered '98' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:24 |
| User entered '36.9' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:39 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:41 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:42 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:44 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:46 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:48 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:50 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:52 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:54 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:56 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:58 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:47:59 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:02 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:03 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:05 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (13)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:08 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:27:57 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 15 (Day 15)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |



FDA-CBER-2022-1614-1685182

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:26 |
| User entered '10 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:27 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:28 |
| User entered '97' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |



FDA-CBER-2022-1614-1685185

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 18:31:05 |



FDA-CBER-2022-1614-1685186

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:30 |
| User entered '37.0' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |



FDA-CBER-2022-1614-1685187

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:39 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:41 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:43 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:45 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:47 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:49 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:51 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:53 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:55 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:48:57 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:49:00 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:49:02 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:49:04 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:49:07 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:49:09 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (14)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:49:10 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:31:05 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 16 (Day 16)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User closed query 'Per source, Day 16 telemedicine visit occurred on 12Sep. Please clarify' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 17:28:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:13 |
| Query 'Per source, Day 16 telemedicine visit occurred on 12Sep. Please clarify' answered with '12SEP2020 is DAY 17, these were just assessed locally on the same day' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:44:29 |
| User opened query 'Per source, Day 16 telemedicine visit occurred on 12Sep. Please clarify' (Site from CRA). | (b) (4), (b) (6) | 23 Mar 2021 17:12:40 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| User closed query 'Please confirm date with source' (Site from CRA). | | 23 Mar 2021 17:09:28 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered '11 Sep 2020' reason for change: Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| Query 'Please confirm date with source' answered with 'UPDATED PER SOURCE' (Site from CRA). | (b) (4), (b) (6) | 25 Jan 2021 18:33:59 |
| User entered '12 Sep 2020' reason for change: Data Entry Error | | 25 Jan 2021 18:33:04 |
| User opened query 'Please confirm date with source' (Site from CRA). | | 15 Jan 2021 14:50:14 |
| User entered '11 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |



FDA-CBER-2022-1614-1685205

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered '1' reason for change: Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:50:18 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:50:33 |
| User entered '91' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 19 Mar 2021 15:50:58 |
| User entered '%' | System | 13 Sep 2020 18:33:30 |



FDA-CBER-2022-1614-1685208

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:50:39 |
| User entered '37.4' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:51:04 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:50:46 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:50:48 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:51:05 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:50:50 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:51:07 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:50:54 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:50:56 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:51:10 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:51:12 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:51:00 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:51:15 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:51:17 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |



FDA-CBER-2022-1614-1685222

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | (b) (4) Gerardo Pena (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | (b) (4) Gerardo Pena (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | (b) (4) Douglas Denham (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 15 Jan 2021 14:51:19 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:51:21 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (15)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:28:23 |
| DataPoint Un-verified. | | 23 Mar 2021 17:11:32 |
| DataPoint Verified. | | 23 Mar 2021 17:09:25 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User entered empty; reason for change Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 19 Mar 2021 15:50:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:51:23 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:33:30 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 17 (Day 17)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |



FDA-CBER-2022-1614-1685226

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:51:56 |
| User entered '12 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:51:59 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |



FDA-CBER-2022-1614-1685228

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:02 |
| User entered '97' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:07 |
| User entered '36.8' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |



FDA-CBER-2022-1614-1685231

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:53 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:11 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:13 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |



FDA-CBER-2022-1614-1685234

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:55 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:16 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |



FDA-CBER-2022-1614-1685236

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:57 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:22 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |



FDA-CBER-2022-1614-1685238

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:24 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |



FDA-CBER-2022-1614-1685239

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:59 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:53:00 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:41 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:53:03 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:53:04 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:53:07 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:53:09 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (16)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:52:44 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 18:36:09 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 18 (Day 18)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |



FDA-CBER-2022-1614-1685248

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:53:59 |
| User entered '13 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:01 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |



FDA-CBER-2022-1614-1685250

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:03 |
| User entered '100' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 13 Sep 2020 19:28:48 |



FDA-CBER-2022-1614-1685252

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:04 |
| User entered '36.7' C | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |



FDA-CBER-2022-1614-1685253

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:22 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:24 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:25 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |



FDA-CBER-2022-1614-1685256

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:27 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |



FDA-CBER-2022-1614-1685257

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:29 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:31 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:17 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:19 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |



FDA-CBER-2022-1614-1685261

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:33 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:35 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:37 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:40 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:43 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |



FDA-CBER-2022-1614-1685266

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:46 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:47 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (17)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:54:51 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 13 Sep 2020 19:28:48 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 19 (Day 19)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:55:28 |
| User entered '14 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:55:31 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |



FDA-CBER-2022-1614-1685272

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:55:33 |
| User entered '97' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 14 Sep 2020 19:06:23 |



FDA-CBER-2022-1614-1685274

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:55:49 |
| User entered '37.1' C | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |



FDA-CBER-2022-1614-1685275

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:08 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:10 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:14 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |



FDA-CBER-2022-1614-1685278

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:15 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |



FDA-CBER-2022-1614-1685279

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:55:54 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |



FDA-CBER-2022-1614-1685280

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:55:59 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |



FDA-CBER-2022-1614-1685281

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:18 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:04 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |



FDA-CBER-2022-1614-1685283

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:20 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:21 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:27 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:31 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:33 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |



FDA-CBER-2022-1614-1685288

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:36 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:38 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (18)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:56:39 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 14 Sep 2020 19:06:23 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 20 (Day 20)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:57:58 |
| User entered '15 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:58:01 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |



FDA-CBER-2022-1614-1685294

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:58:05 |
| User entered '97' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 15 Sep 2020 20:46:54 |



FDA-CBER-2022-1614-1685296

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Please confirm data with source' (Site from CRA). | (b) (4), (b) (6) | 23 Mar 2021 17:13:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:13:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| Query 'Please confirm data with source' answered with 'UPDATED PER SOURCE' (Site from CRA). | (b) (4), (b) (6) | 25 Jan 2021 18:35:22 |
| User entered '36.0' C reason for change: Data Entry Error | | 25 Jan 2021 18:35:11 |
| User opened query 'Please confirm data with source' (Site from CRA). | | 15 Jan 2021 14:58:25 |
| User entered '37.0' C | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |



FDA-CBER-2022-1614-1685297

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:58:56 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:58:44 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:59:01 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |



FDA-CBER-2022-1614-1685300

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:59:03 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:58:47 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |



FDA-CBER-2022-1614-1685302

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:59:06 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:59:15 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:58:50 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |



FDA-CBER-2022-1614-1685305

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:59:19 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:59:21 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:59:23 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:59:24 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:59:27 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:59:29 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:59:30 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (19)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:58:53 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 15 Sep 2020 20:46:54 |



FDA-CBER-2022-1614-1685313

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 21 (Day 21)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:10 |
| User entered '16 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |



FDA-CBER-2022-1614-1685315

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:11 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |



FDA-CBER-2022-1614-1685316

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:13 |
| User entered '94' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 16 Sep 2020 21:02:42 |



FDA-CBER-2022-1614-1685318

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:15 |
| User entered '37.0' C | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |



FDA-CBER-2022-1614-1685319

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:35 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:36 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:40 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |



FDA-CBER-2022-1614-1685322

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:42 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:22 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |



FDA-CBER-2022-1614-1685324

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:44 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:46 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:24 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |



FDA-CBER-2022-1614-1685327

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:48 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |



FDA-CBER-2022-1614-1685328

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:51 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:53 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:54 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:56 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:58 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:00:59 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (20)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:01:01 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 16 Sep 2020 21:02:42 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 22 (Day 22)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:01:33 |
| User entered '17 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |



FDA-CBER-2022-1614-1685337

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:01:38 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |



FDA-CBER-2022-1614-1685338

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:01:36 |
| User entered '97' reason for change: Data Entry Error | Gerardo Pena (b) (4) (b) (4) | 30 Sep 2020 20:21:33 |
| User entered '95' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |



FDA-CBER-2022-1614-1685339

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 17 Sep 2020 21:49:22 |



FDA-CBER-2022-1614-1685340

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:12 |
| User entered '36.8' C | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |



FDA-CBER-2022-1614-1685341

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:35 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:37 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:39 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |



FDA-CBER-2022-1614-1685344

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:41 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:30 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |



FDA-CBER-2022-1614-1685346

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:43 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:44 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:32 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |



FDA-CBER-2022-1614-1685349

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:46 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |



FDA-CBER-2022-1614-1685350

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:49 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |



FDA-CBER-2022-1614-1685351

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:50 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:52 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:54 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:55 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:57 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |



FDA-CBER-2022-1614-1685356

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (21)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:02:59 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 17 Sep 2020 21:49:22 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 23 (Day 23)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |
| User entered 'Day 22 (Day 22)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:21 |
| User entered '18 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |



FDA-CBER-2022-1614-1685359

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:23 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:24 |
| User entered '98' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 18 Sep 2020 16:16:20 |



FDA-CBER-2022-1614-1685362

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:26 |
| User entered '36.2' C | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:40 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:42 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:44 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |



FDA-CBER-2022-1614-1685366

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:46 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:34 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |



FDA-CBER-2022-1614-1685368

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:48 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:50 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:37 |
| User entered 'Mild (Mild)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:51 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:53 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:54 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:57 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:03:58 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:04:00 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:04:02 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (22)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:04:04 |
| User entered 'None (None)' | Kristy Trevino (b) (4) (b) (4) | 18 Sep 2020 16:16:20 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 1 (Day 1)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:11:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 10 Nov 2020 10:59:44 |
| User entered '27 Aug 2020' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| Query 'Data is required. Please complete.' answered with 'visit was not done.. Subject was unreachable ' (Site from System). | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:57 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Sep 2020 21:54:49 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:11:03 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:10:28 |
| User entered '98' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685383

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 06 Nov 2020 17:24:22 |
| User entered empty. | System | 21 Sep 2020 21:54:49 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:10:30 |
| User entered '37.0' C reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:18 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:20 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:21 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:23 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685389

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:26 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685390

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:28 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:32 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:33 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:35 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:36 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:38 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:40 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685399

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:12:49 |
| User entered 'None (None)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (23)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Severity not specified in source. Please rectify' (Site from CRA). | | 23 Mar 2021 17:14:10 |
| DataPoint Verified. | | 23 Mar 2021 17:14:08 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| Query 'Severity not specified in source. Please rectify' answered with 'severity added to esouce note on bottom of symptoms/severity assessment' (Site from CRA). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 20:06:41 |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Jan 2021 18:38:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | | 25 Jan 2021 18:38:09 |
| User opened query 'Severity not specified in source. Please rectify' (Site from CRA). | | 15 Jan 2021 15:13:34 |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:24:22 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 24 (Day 24)' reason for change: Data Entry Error | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:28:17 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685402

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Source still states that telemedicine visit did not occur on Day 24. please reconcile' (Site from CRA). | | 13 Apr 2021 17:26:17 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| Query 'Source still states that telemedicine visit did not occur on Day 24. please reconcile' answered with '"Assessment Not Done" is marked. This is correct' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:49:27 |
| User opened query 'Source still states that telemedicine visit did not occur on Day 24. please reconcile' (Site from CRA). | (b) (4), (b) (6) | 23 Mar 2021 17:15:24 |
| User closed query 'If visit did not occur, please specify in source' (Site from CRA). | | 23 Mar 2021 17:15:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:17:03 |
| Query 'If visit did not occur, please specify in source' answered with 'SOURCE UPDATED' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 18:39:25 |
| User opened query 'If visit did not occur, please specify in source' (Site from CRA). | (b) (4), (b) (6) | 15 Jan 2021 15:06:31 |
| User closed query 'Per CDM: Previous response confirms that assessment was not done. Please review and update the corresponding data field accordingly.' (Site from DM). | (b) (4) | 31 Dec 2020 03:38:53 |
| Query 'Per CDM: Previous response confirms that assessment was not done. Please review and update the corresponding data field accordingly.' answered with 'updated' (Site from DM). | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:33:27 |
| User entered '19 Sep 2020' reason for change: Data Entry Error | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:25:16 |
| User opened query 'Per CDM: Previous response confirms that assessment was not done. Please review and update the corresponding data field accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 11:04:04 |
| Query 'Per CDM: Previous response confirmed that assesments was not done..Please review and update the corresponding data field accordingly.' canceled (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 11:03:03 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| User opened query 'Per CDM: Previous response confirmed that assesments was not done..Please review and update the corresponding data field accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 11:02:52 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 10 Nov 2020 11:00:13 |
| Query 'Data is required. Please complete.' answered with 'visit not done' (Site from System). | Dawn Killian (b) (4) (b) (4) | 23 Sep 2020 20:46:09 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Sep 2020 21:54:49 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered '1' reason for change: Data Entry Error | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:25:16 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685405

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685406

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685408

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685409

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685410

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685411

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685412

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685414

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685415

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685416

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685417

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685419

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685421

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685422

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685423

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (24)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:25:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685424

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 26 (Day 26)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 10 Oct 2020 04:14:01 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:07:57 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 21 Sep 2020 21:56:35 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Sep 2020 21:56:35 |
| User entered '21 Sep 2020' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Sep 2020 21:54:49 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:07:59 |
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685427

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:01 |
| User entered '97' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '%' | System | 21 Sep 2020 21:56:35 |
| User entered empty. | System | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685429

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:02 |
| User entered '36.4' C reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 10 Oct 2020 04:14:12 |
| User entered '36.8' C reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |



FDA-CBER-2022-1614-1685430

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:18 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:20 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:22 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:23 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:26 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:28 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:12 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:32 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:34 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:14 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 10 Oct 2020 04:15:27 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:35 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 10 Oct 2020 04:15:13 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:37 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:38 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:40 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (25)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 15:08:41 |
| User entered 'None (None)' reason for change: Data Entry Error | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:56:35 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 21 Sep 2020 21:54:49 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Day 25 (Day 25)' reason for change: Data Entry Error | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:33:08 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User closed query 'Source still states that telemedicine visit did not occur on Day 25. Additionally, 20Dec2020 does not allign with current symptom log day. please reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 17:26:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:26:41 |
| Query 'Source still states that telemedicine visit did not occur on Day 25. Additionally, 20Dec2020 does not allign with current symptom log day. please reconcile. ' answered with '"Assessment not done" is marked, which is correct. Date corrected.' (Site from CRA). | Antonio Gutierrez (b) (4) (b) (4) | 05 Apr 2021 20:51:18 |
| Signature has been broken. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:51:04 |
| User entered '20 Sep 2020' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:51:04 |
| User opened query 'Source still states that telemedicine visit did not occur on Day 25. Additionally, 20Dec2020 does not allign with current symptom log day. please reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 23 Mar 2021 17:17:55 |
| User closed query 'If visit did not occur, please specify in source.' (Site from CRA). | | 23 Mar 2021 17:17:55 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| Query 'If visit did not occur, please specify in source. answered with 'SOURCE UPDATED' (Site from CRA). | (b) (4), (b) (6) | 25 Jan 2021 18:40:09 |
| User opened query 'If visit did not occur, please specify in source.' (Site from CRA). | | 15 Jan 2021 15:07:28 |
| User entered '20 Dec 2020' | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685448

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered '1' | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685449

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685450

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685451

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685452

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685454

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685455

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685456

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685457

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685458

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685459

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685460

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685461

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685462

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685463

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685464

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685465

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685466

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685467

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Symptom Log (26)**
**Generated On: 11 Aug 2021 22:21:07**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:26:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 29 Dec 2020 22:26:43 |



FDA-CBER-2022-1614-1685468

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID Diagnostic Test**
**Generated On: 11 Aug 2021 22:21:07**
Date of Visit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:01:25 |
| User closed query 'Per GCL Lab Reconciliation: Swab Sample dated 28Aug2020 is recorded under Illness visit in EDC, however a Saliva samples are also reported under Illness visit dated in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM). | | 04 Jan 2021 05:21:10 |
| Query 'Per GCL Lab Reconciliation: Swab Sample dated 28Aug2020 is recorded under Illness visit in EDC, however a Saliva samples are also reported under Illness visit dated in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' answered with 'Date of Visit updated to reflect source. First saliva sample collected on 29Aug2020' (Site from DM). | | 31 Dec 2020 16:50:55 |
| User entered '27 Aug 2020' reason for change: Data Entry Error | | 31 Dec 2020 16:49:50 |
| User opened query 'Per GCL Lab Reconciliation: Swab Sample dated 28Aug2020 is recorded under Illness visit in EDC, however a Saliva samples are also reported under Illness visit dated in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM). | | 25 Oct 2020 21:21:41 |
| User entered '28 Aug 2020' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:03:11 |



FDA-CBER-2022-1614-1685469

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID Diagnostic Test**
**Generated On: 11 Aug 2021 22:21:07**
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:01:21 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:03:11 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID Diagnostic Test**
**Generated On: 11 Aug 2021 22:21:07**
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 19:29:43 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User closed query 'Per CDM: As per CCGs, data should be indicated as "Yes or NO". Please review and update accordingly' (Site from DM). | (b) (4), (b) (6) | 21 Dec 2020 13:47:32 |
| Query 'Per CDM: As per CCGs, data should be indicated as "Yes or NO". Please review and update accordingly' answered with 'Swab never resulted per PPD! Potentially lost sample by PPD Lab.' (Site from DM). | Nathan Cortez (b) (4) | 06 Nov 2020 17:25:29 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 02 Nov 2020 08:31:55 |
| User opened query 'Per CDM: As per CCGs, data should be indicated as "Yes or NO". Please review and update accordingly' (Site from DM). | | 02 Nov 2020 08:29:40 |
| Query 'Data is required. Please complete.' answered with 'Results not received as of yet ' (Site from System). | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:05:15 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 28 Aug 2020 22:03:11 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:03:11 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID Diagnostic Test**
**Generated On: 11 Aug 2021 22:21:07**
Date of Test

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 14 Apr 2021 19:29:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User closed query 'Per GCL Lab Reconciliation requery: Swab: Thank you for your response," Accession Number: "1F60BS1"; however, please provide the tracking details in query response for tracking purpose.' (Site from DM). | (b) (4), (b) (6) | 17 Feb 2021 05:28:43 |
| Query 'Per GCL Lab Reconciliation requery: Swab: Thank you for your response," Accession Number: "1F60BS1"; however, please provide the tracking details in query response for tracking purpose.' answered with 'Tracking details unavailable per site lab' (Site from DM). | Victoria Hernandez (b) (4) (b) (4) | 09 Feb 2021 18:10:46 |
| User opened query 'Per GCL Lab Reconciliation requery: Swab: Thank you for your response," Accession Number: "1F60BS1"; however, please provide the tracking details in query response for tracking purpose.' (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 05:21:36 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 27-AUG-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample 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). | | 19 Jan 2021 05:21:36 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 27-AUG-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample 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 'Specimen received by PPD 09-SEP-2020. Accession Number: 1F60BS1' (Site from DM). | Gerardo Pena (b) (4) (b) (4) | 05 Jan 2021 17:10:43 |



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**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID Diagnostic Test**
**Generated On: 11 Aug 2021 22:21:07**
Date of Test

| Audit | User | Time (GMT) |
|---|---|---|
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 27-AUG-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample 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) | 05 Jan 2021 12:21:59 |
| User entered '27 Aug 2020' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:03:11 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID Diagnostic Test**
**Generated On: 11 Aug 2021 22:21:07**
Type of Test Performed

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:02:02 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:03:11 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID Diagnostic Test**
**Generated On: 11 Aug 2021 22:21:07**
Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:30:37 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:03:11 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID Diagnostic Test**
**Generated On: 11 Aug 2021 22:21:07**

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) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 14:02:09 |
| User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System). | System | 11 Sep 2020 15:25:40 |
| User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System). | System | 28 Aug 2020 22:03:11 |
| User entered 'No (N)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:03:11 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID Diagnostic Test**
**Generated On: 11 Aug 2021 22:21:07**
Lab/ Institution Test Performed

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:30:35 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty; reason for change Data Entry Error | Nathan Cortez (b) (4) | 11 Sep 2020 15:25:40 |
| User entered 'Test performed in home of patient' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:03:11 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID Diagnostic Test**
**Generated On: 11 Aug 2021 22:21:07**
CLIA Certified?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:30:33 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty; reason for change Data Entry Error | Nathan Cortez (b) (4) | 11 Sep 2020 15:25:40 |
| User entered 'No (N)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:03:11 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: COVID Diagnostic Test**
**Generated On: 11 Aug 2021 22:21:07**
COVID-19 Positive (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |

**US3292241**
**Folder: Covid-19 Assessment 27 Aug 2020**
**Form: Generate Next COVID-19 Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Generate Next COVID-19 Assessment

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 14:06:17 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'No (N)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 17:25:45 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 22:05:45 |

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (1)**
**Generated On: 11 Aug 2021 22:21:07**
Visit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User accepted default value 'Day 3 (Day 3)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



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**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (1)**
**Generated On: 11 Aug 2021 22:21:07**
Was Saliva Collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 12 Apr 2021 14:14:06 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685482

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (1)**
**Generated On: 11 Aug 2021 22:21:07**
Date of Collection

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 12 Apr 2021 14:14:06 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered '29 Aug 2020' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685483

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (2)**
**Generated On: 11 Aug 2021 22:21:07**
Visit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User accepted default value 'Day 5 (Day 5)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (2)**
**Generated On: 11 Aug 2021 22:21:07**
Was Saliva Collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 12 Apr 2021 14:14:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685485

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (2)**
**Generated On: 11 Aug 2021 22:21:07**
Date of Collection

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 12 Apr 2021 14:14:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered '31 Aug 2020' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685486

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (3)**
**Generated On: 11 Aug 2021 22:21:07**
Visit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User accepted default value 'Day 7 (Day 7)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (3)**
**Generated On: 11 Aug 2021 22:21:07**
Was Saliva Collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 12 Apr 2021 14:16:32 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685488

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (3)**
**Generated On: 11 Aug 2021 22:21:07**
Date of Collection

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 12 Apr 2021 14:16:32 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered '02 Sep 2020' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685489

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (4)**
**Generated On: 11 Aug 2021 22:21:07**
Visit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User accepted default value 'Day 9 (Day 9)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (4)**
**Generated On: 11 Aug 2021 22:21:07**
Was Saliva Collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 12 Apr 2021 14:16:53 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685491

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (4)**
**Generated On: 11 Aug 2021 22:21:07**
Date of Collection

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 12 Apr 2021 14:16:53 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered '04 Sep 2020' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685492

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (5)**
**Generated On: 11 Aug 2021 22:21:07**
Visit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User accepted default value 'Day 14 (Day 14)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (5)**
**Generated On: 11 Aug 2021 22:21:07**
Was Saliva Collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 19 Apr 2021 19:39:36 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685494

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (5)**
**Generated On: 11 Aug 2021 22:21:07**
Date of Collection

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 19 Apr 2021 19:39:36 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered '09 Sep 2020' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685495

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (6)**
**Generated On: 11 Aug 2021 22:21:07**
Visit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User accepted default value 'Day 21 (Day 21)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685496

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (6)**
**Generated On: 11 Aug 2021 22:21:07**
Was Saliva Collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 12 Apr 2021 14:17:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685497

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (6)**
**Generated On: 11 Aug 2021 22:21:07**
Date of Collection

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 12 Apr 2021 14:17:26 |
| User closed query '□Per GCL Lab Reconciliation Requery: Saliva: Thank you for confirming. Please provide Accession number and tracking number for tracking the sample in PPD as the sample is still missing.' (Site from DM). | | 26 Feb 2021 13:00:26 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| Query '□Per GCL Lab Reconciliation Requery: Saliva: Thank you for confirming. Please provide Accession number and tracking number for tracking the sample in PPD as the sample is still missing.' answered with '1F60BS1' (Site from DM). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:54:00 |
| User opened query '□Per GCL Lab Reconciliation Requery: Saliva: Thank you for confirming. Please provide Accession number and tracking number for tracking the sample in PPD as the sample is still missing.' (Site from DM). | (b) (4), (b) (6) | 01 Feb 2021 12:52:33 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16SEP2020 is recorded under Illness Visit Day 21 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). | | 01 Feb 2021 12:52:33 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16SEP2020 is recorded under Illness Visit Day 21 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 'date already entered.' (Site from DM). | | 25 Jan 2021 21:36:36 |

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (6)**
**Generated On: 11 Aug 2021 22:21:07**
Date of Collection

| Audit | User | Time (GMT) |
|---|---|---|
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16SEP2020 is recorded under Illness Visit Day 21 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.<br />' (Site from DM). | (b) (4), (b) (6) | 04 Dec 2020 10:45:54 |
| User entered '16 Sep 2020' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (7)**
**Generated On: 11 Aug 2021 22:21:07**
Visit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User accepted default value 'Day 28 (Day 28)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (7)**
**Generated On: 11 Aug 2021 22:21:07**
Was Saliva Collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 12 Apr 2021 14:17:40 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'No (N)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685501

**US3292241**
**Folder: Illness Visit (1)**
**Form: Saliva Collection (7)**
**Generated On: 11 Aug 2021 22:21:07**
Date of Collection

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 12 Apr 2021 14:17:40 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Nathan Cortez (b) (4) | 06 Nov 2020 18:01:31 |



FDA-CBER-2022-1614-1685502

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was this visit performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:37:51 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 06 Nov 2020 17:58:23 |



FDA-CBER-2022-1614-1685503

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:37:52 |
| User entered '27 Aug 2020' | Nathan Cortez (b) (4) | 06 Nov 2020 17:58:23 |



FDA-CBER-2022-1614-1685504

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:37:54 |
| User entered 'Home (Home)' | Nathan Cortez (b) (4) | 06 Nov 2020 17:58:23 |

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Folder OID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'SICKD1' | System | 06 Nov 2020 17:58:23 |



FDA-CBER-2022-1614-1685506

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:10 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:25 |

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:10 |
| User entered '27 Aug 2020' | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:25 |



FDA-CBER-2022-1614-1685508

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:10 |
| User entered '13:05' | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:25 |

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '27 Aug 2020 13:05' | System | 06 Nov 2020 17:59:25 |

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Height *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:10 |
| User entered '167.6' cm | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:25 |
| DataPoint set to visible. | System | 06 Nov 2020 17:58:23 |

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Weight *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:10 |
| User entered '141.2' kg | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:25 |
| DataPoint set to visible. | System | 06 Nov 2020 17:58:23 |

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:10 |
| User entered '37.0' C | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:25 |



FDA-CBER-2022-1614-1685513

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:10 |
| User entered 'Oral (Oral)' | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:25 |



FDA-CBER-2022-1614-1685514

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:10 |
| User entered empty. | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:25 |

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:10 |
| User entered '74' | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:25 |



FDA-CBER-2022-1614-1685516

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'bpm' | System | 06 Nov 2020 17:59:25 |



FDA-CBER-2022-1614-1685517

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:10 |
| User entered '18' | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:25 |



FDA-CBER-2022-1614-1685518

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'breaths/min' | System | 06 Nov 2020 17:59:25 |



FDA-CBER-2022-1614-1685519

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:10 |
| User entered '145' | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:25 |



FDA-CBER-2022-1614-1685520

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'mmHg' | System | 06 Nov 2020 17:59:25 |



FDA-CBER-2022-1614-1685521

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:10 |
| User entered '79' | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:25 |



FDA-CBER-2022-1614-1685522

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'mmHg' | System | 06 Nov 2020 17:59:25 |



FDA-CBER-2022-1614-1685523

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Height (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685524

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 11 Aug 2021 22:21:07**
Weight (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685525

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Physical Examination**
**Generated On: 11 Aug 2021 22:21:07**
Was the physical examination performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:42 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:55 |

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Physical Examination**
**Generated On: 11 Aug 2021 22:21:07**
Date of examination *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:42:42 |
| User entered '27 Aug 2020' | Nathan Cortez (b) (4) | 06 Nov 2020 17:59:55 |

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**
**Generated On: 11 Aug 2021 22:21:07**
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:43:37 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:00:12 |

**US3292241**
**Folder: Illness Visit Day 1 (1)**
**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**
**Generated On: 11 Aug 2021 22:21:07**
Date of Collection

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Jan 2021 13:43:37 |
| User entered '27 Aug 2020' | Nathan Cortez (b) (4) | 06 Nov 2020 18:00:12 |

**US3292241**
**Folder: Convalescence Visit Day 28 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was this visit performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:07:32 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'No (N)' | Nathan Cortez (b) (4) | 06 Nov 2020 18:00:20 |

**US3292241**
**Folder: Convalescence Visit Day 28 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:07:32 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Nathan Cortez (b) (4) | 06 Nov 2020 18:00:20 |



FDA-CBER-2022-1614-1685531

**US3292241**
**Folder: Convalescence Visit Day 28 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 13 Apr 2021 17:07:32 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered empty. | Nathan Cortez (b) (4) | 06 Nov 2020 18:00:20 |



FDA-CBER-2022-1614-1685532

**US3292241**
**Folder: Convalescence Visit Day 28 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Folder OID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'SICKD28' | System | 06 Nov 2020 18:00:20 |



FDA-CBER-2022-1614-1685533

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was this visit performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:29 |
| User entered 'No (N)' | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:42:36 |



FDA-CBER-2022-1614-1685534

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:29 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:42:36 |

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:29 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:42:36 |



FDA-CBER-2022-1614-1685536

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Visit Date**
**Generated On: 11 Aug 2021 22:21:07**
Folder OID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered 'UNBLND_DECIDE' | System | 31 Mar 2021 13:42:36 |

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Generated On: 11 Aug 2021 22:21:07**
Date of updated informed consent *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:38 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:43:03 |



FDA-CBER-2022-1614-1685538

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Generated On: 11 Aug 2021 22:21:07**
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:38 |
| User entered '1' | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:43:03 |



FDA-CBER-2022-1614-1685539

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Generated On: 11 Aug 2021 22:21:07**
Was the participant unblinded?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:38 |
| User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System). | System | 31 Mar 2021 13:44:25 |
| Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System). | System | 31 Mar 2021 13:44:25 |
| User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System). | System | 31 Mar 2021 13:43:03 |
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:43:03 |



FDA-CBER-2022-1614-1685540

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Generated On: 11 Aug 2021 22:21:07**
Under what version of the Protocol was the Participant unblinded?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:38 |
| User entered 'Amendment 5 (Amendment 5)' | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:43:03 |



FDA-CBER-2022-1614-1685541

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Generated On: 11 Aug 2021 22:21:07**
Date of unblinding *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:38 |
| User entered '31 Dec 2020' | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:43:03 |



FDA-CBER-2022-1614-1685542

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Generated On: 11 Aug 2021 22:21:07**
Participant randomization assignment

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:38 |
| User entered 'mRNA-1273 (mRNA-1273)' | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:43:03 |



FDA-CBER-2022-1614-1685543

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Generated On: 11 Aug 2021 22:21:07**
Actual Dose 1

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:38 |
| User entered 'mRNA-1273 (mRNA-1273)' reason for change: Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:44:25 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:43:03 |



FDA-CBER-2022-1614-1685544

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Generated On: 11 Aug 2021 22:21:07**
Actual Dose 2

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:38 |
| User entered 'Not Administered (NA)' reason for change: Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:44:25 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:43:03 |



FDA-CBER-2022-1614-1685545

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Generated On: 11 Aug 2021 22:21:07**
Will participant receive mRNA-1273?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:38 |
| User entered 'No (N)' reason for change: Per Query Resolution | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:44:25 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:43:03 |

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Generated On: 11 Aug 2021 22:21:07**
Placebo Only Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 31 Mar 2021 13:43:03 |



FDA-CBER-2022-1614-1685547

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Generated On: 11 Aug 2021 22:21:07**
Continuing with mRNA-1273

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 31 Mar 2021 13:43:03 |



FDA-CBER-2022-1614-1685548

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:50 |
| User entered 'No (N)' | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:44:30 |

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Collection date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:50 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:44:30 |

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Collection time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:16:50 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:44:30 |



FDA-CBER-2022-1614-1685551

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 11 Aug 2021 22:21:07**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 31 Mar 2021 13:44:30 |



FDA-CBER-2022-1614-1685552

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (Single)**
**Generated On: 11 Aug 2021 22:21:07**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:17:00 |
| User entered 'No (N)' | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:44:33 |

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (Single)**
**Generated On: 11 Aug 2021 22:21:07**
Collection date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:17:00 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:44:33 |



FDA-CBER-2022-1614-1685554

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (Single)**
**Generated On: 11 Aug 2021 22:21:07**
Collection time *(00:00 - 23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:17:00 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:44:33 |



FDA-CBER-2022-1614-1685555

**US3292241**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (Single)**
**Generated On: 11 Aug 2021 22:21:07**
Collection Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 31 Mar 2021 13:44:33 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events Summary**
**Generated On: 11 Aug 2021 22:21:07**
Did the participant experience any adverse events?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Per DM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, 'Headache', 'Joint aches in several joints', 'Muscle aches all over' and 'Nausea/Vomiting' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM). | | 26 Apr 2021 09:25:54 |
| Query 'Per DM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, 'Headache', 'Joint aches in several joints', 'Muscle aches all over' and 'Nausea/Vomiting' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'added' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 23 Apr 2021 10:43:32 |
| User opened query 'Per DM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, 'Headache', 'Joint aches in several joints', 'Muscle aches all over' and 'Nausea/Vomiting' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM). | (b) (4), (b) (6) | 18 Apr 2021 17:24:14 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:28:18 |
| User closed query 'Please add "Tooth infection" per paper source V2 D29.' (Site from CRA). | | 09 Apr 2021 17:28:16 |

**US3292241**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:21:07**

Did the participant experience any adverse events?

| Audit | User | Time (GMT) |
|---|---|---|
| User closed query 'Please add AE of ABDOMINAL PAIN to EDC. ' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 17:28:15 |
| Query 'Please add "Tooth infection" per paper source V2 D29.' answered with 'This was updated to bilateral lymphadenitis ' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:52:00 |
| Query 'Please add AE of ABDOMINAL PAIN to EDC. ' answered with 'done' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:51:44 |
| User opened query 'Please add "Tooth infection" per paper source V2 D29.' (Site from CRA). | (b) (4), (b) (6) | 11 Feb 2021 20:01:59 |
| User opened query 'Please add AE of ABDOMINAL PAIN to EDC. ' (Site from CRA). | | 10 Feb 2021 19:06:31 |
| User entered 'Yes (Y)' | | 27 Oct 2020 18:24:12 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685559

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 17:29:41 |
| User closed query 'Per DM CLR: Please specify the location of Lymphadenitis. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM). | | 06 Apr 2021 15:08:49 |
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenitis, LLT: Lymphadenitis cervical - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 06 Apr 2021 12:40:43 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 06 Apr 2021 12:40:43 |
| Data point term sent to Coder | System | 05 Apr 2021 20:38:29 |
| Query 'Per DM CLR: Please specify the location of Lymphadenitis. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated to neck' (Site from DM). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:37:54 |
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:37:45 |
| Coding entries removed. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:37:45 |
| User entered 'BILATERAL LYMPHADENITIS (Neck)' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:37:45 |
| User opened query 'Per DM CLR: Please specify the location of Lymphadenitis. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 03 Apr 2021 11:02:52 |



FDA-CBER-2022-1614-1685560

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:53:31 |
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenitis, LLT: Lymphadenitis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Feb 2021 12:14:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Feb 2021 12:14:46 |
| User closed query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location and laterality of LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL to vaccination arm). Update accordingly. Otherwise, clarify. ' (Site from DM). | (b) (4), (b) (6) | 09 Feb 2021 10:43:54 |
| Query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location and laterality of LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL to vaccination arm). Update accordingly. Otherwise, clarify. ' answered with 'updated ae term' (Site from DM). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:40:05 |
| Data point term sent to Coder | System | 08 Feb 2021 19:39:43 |
| Coding entries removed. | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:39:38 |
| User entered 'Bilateral lymphadenitis' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:39:38 |
| User opened query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location and laterality of LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL to vaccination arm). Update accordingly. Otherwise, clarify. ' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:19:50 |



FDA-CBER-2022-1614-1685561

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Swollen lymph nodes - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Oct 2020 18:33:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Oct 2020 18:33:24 |
| Data point term sent to Coder | System | 27 Oct 2020 18:33:05 |
| User entered 'SWOLLEN LYMPHNODES' | (b) (4), (b) (6) | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685562

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:53:35 |
| User entered 'No (N)' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685563

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:53:37 |
| User entered 'No (N)' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685564

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| Query 'Answer not present in source. please review and reconcile.' canceled (Site from CRA). | (b) (4), (b) (6) | 31 Mar 2021 20:56:26 |
| DataPoint Verified. | | 31 Mar 2021 20:56:22 |
| User opened query 'Answer not present in source. please review and reconcile.' (Site from CRA). | | 10 Feb 2021 18:54:15 |
| User entered 'No (N)' | | 27 Oct 2020 18:32:32 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 18:54:34 |
| User entered '21 Aug 2020' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685566

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:54:38 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 02 Nov 2020 15:38:20 |
| Query 'Data is required. Please provide.' answered with 'START TIME IS UNKNOWN' (Site from System). | | 27 Oct 2020 18:33:36 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 27 Oct 2020 18:32:32 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685567

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 27 Oct 2020 18:32:32 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:54:40 |
| User entered 'No (N)' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685569

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:54:42 |
| User entered '27 Oct 2020' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685570

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:54:46 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 02 Nov 2020 15:37:54 |
| Query 'Data is required. Please provide.' answered with 'END TIME IS UNKNOWN' (Site from System). | | 27 Oct 2020 18:33:44 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 27 Oct 2020 18:32:32 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685571

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | | 27 Oct 2020 18:32:32 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:54:55 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | | 27 Oct 2020 18:32:32 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:54:57 |
| User entered 'No (N)' | | 27 Oct 2020 18:32:32 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:54:59 |
| User entered '0' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685575

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:55:01 |
| User entered '0' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685576

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:55:03 |
| User entered '0' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685577

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:55:05 |
| User entered empty. | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685578

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:55:07 |
| User entered empty. | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685579

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:55:09 |
| User entered empty. | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685580

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:55:11 |
| User entered empty. | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685581

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:55:13 |
| User entered '0' | | 27 Oct 2020 18:32:32 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:55:16 |
| User entered '0' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685583

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:55:20 |
| User entered '0' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685584

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 18:56:22 |
| User entered 'Related (RELATED)' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685585

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:56:24 |
| User entered 'Not Related (NOT RELATED)' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685586

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 18:56:28 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 16:23:32 |
| User entered 'None (NONE)' | (b) (4), (b) (6) | 27 Oct 2020 18:32:32 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 17:18:49 |
| DataPoint Un-verified. | Dawn Killian (b) (4) | 13 Apr 2021 17:07:49 |
| User entered '1' reason for change: Per Query Resolution | (b) (4) Dawn Killian (b) (4) (b) (4) | 13 Apr 2021 17:07:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:56:35 |
| User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#14) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM). | | 30 Mar 2021 14:03:54 |
| Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#14) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM). | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:28:23 |
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:28:15 |
| User entered '0' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:28:15 |
| User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#14) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM). | (b) (4), (b) (6) | 02 Mar 2021 04:44:59 |
| DataPoint Verified. | | 10 Feb 2021 18:56:29 |
| User entered '1' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685588

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User closed query 'Per source, "Other Action Taken" is "None. Please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 17:18:53 |
| DataPoint Verified. | | 13 Apr 2021 17:18:51 |
| Query 'Per source, "Other Action Taken" is "None. Please review and reconcile. ' answered with 'updated' (Site from CRA). | Dawn Killian (b) (4) (b) (4) | 13 Apr 2021 17:07:54 |
| User entered '0' reason for change: Per Query Resolution | Dawn Killian (b) (4) (b) (4) | 13 Apr 2021 17:07:49 |
| User opened query 'Per source, "Other Action Taken" is "None. Please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 17:31:08 |
| DataPoint Un-verified. | | 09 Apr 2021 17:30:45 |
| DataPoint Verified. | | 09 Apr 2021 17:29:46 |
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:28:15 |
| User entered '1' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:28:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:56:32 |
| User entered '0' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685589

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:56:34 |
| User entered '0' | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685590

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:56:40 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | | 27 Oct 2020 18:32:32 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:56:42 |
| User entered empty. | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685592

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 18:56:44 |
| User entered empty. | | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685593

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685594

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 27 Oct 2020 18:32:32 |



FDA-CBER-2022-1614-1685595

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:52:17 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685596

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685597

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 18:57:12 |
| User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Ocular disorders NEC, PT: Eye swelling, LLT: Eye swelling - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Oct 2020 22:30:32 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Oct 2020 22:30:32 |
| Data point term sent to Coder | System | 27 Oct 2020 18:36:08 |
| User entered 'LEFT Eye swelling' | (b) (4), (b) (6) | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685598

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:57:14 |
| User entered 'No (N)' | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685599

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:57:15 |
| User entered 'No (N)' | | 27 Oct 2020 18:35:43 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:56:51 |
| Query 'Answer not present in source. Please review and reconcile. ' canceled (Site from CRA). | | 31 Mar 2021 20:56:50 |
| User opened query 'Answer not present in source. Please review and reconcile. ' (Site from CRA). | | 10 Feb 2021 18:57:42 |
| User entered 'No (N)' | | 27 Oct 2020 18:35:43 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 18:57:46 |
| User entered '21 Aug 2020' reason for change: Data Entry Error | | 27 Oct 2020 18:36:40 |
| User entered '21 Oct 2020' | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685602

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:57:48 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 02 Nov 2020 15:39:03 |
| Query 'Data is required. Please provide.' answered with 'START TIME IS UNKNOWN' (Site from System). | | 27 Oct 2020 18:37:19 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 27 Oct 2020 18:36:40 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685603

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685604

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:57:51 |
| 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). | | 09 Feb 2021 11:00:35 |
| 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 'status of AE updated' (Site from DM). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:41:09 |
| User entered 'No (N)' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:40:47 |
| 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 08:01:29 |
| User entered 'Yes (Y)' | | 27 Oct 2020 18:35:43 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 18:57:54 |
| 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 | 08 Feb 2021 19:41:29 |
| 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 | 08 Feb 2021 19:41:29 |
| 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 | 08 Feb 2021 19:40:47 |
| User entered '12 Nov 2020' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:40:47 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685606

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 09 Feb 2021 09:28:10 |
| Query 'Data is required. Please provide.' answered with 'unavailable information' (Site from System). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:42:10 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 08 Feb 2021 19:40:47 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:35:43 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685608

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:57:59 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685609

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:01 |
| User entered 'No (N)' | | 27 Oct 2020 18:35:43 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:04 |
| User entered '0' | | 27 Oct 2020 18:35:43 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 18:58:06 |
| User entered '0' | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685612

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:08 |
| User entered '0' | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685613

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:11 |
| User entered empty. | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685614

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:13 |
| User entered empty. | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685615

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:15 |
| User entered empty. | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685616

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:18 |
| User entered empty. | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685617

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:20 |
| User entered '0' | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685618

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:23 |
| User entered '0' | | 27 Oct 2020 18:35:43 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:26 |
| User entered '0' | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685620

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:35 |
| User entered 'Not Related (NOT RELATED)' | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685621

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:37 |
| User entered 'Not Related (NOT RELATED)' | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685622

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:40 |
| User entered 'None (NONE)' | | 27 Oct 2020 18:35:43 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:49 |
| User entered '1' | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685624

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:52 |
| User entered '0' | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685625

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:58:54 |
| User entered '0' | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685626

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 18:59:07 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:41:29 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 27 Oct 2020 18:36:09 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 27 Oct 2020 18:36:09 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error | (b) (4), (b) (6) | 27 Oct 2020 18:36:09 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 27 Oct 2020 18:35:43 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:35:43 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:59:10 |
| User entered empty. | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685628

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 18:59:12 |
| User entered empty. | | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685629

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685630

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 27 Oct 2020 18:35:43 |



FDA-CBER-2022-1614-1685631

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:45 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685632

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685633

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 19:00:42 |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Occipital headache - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Oct 2020 18:45:34 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Oct 2020 18:45:34 |
| Data point term sent to Coder | System | 27 Oct 2020 18:44:21 |
| User entered 'Occipital headache' | (b) (4), (b) (6) | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685634

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:00:50 |
| User entered 'No (N)' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685635

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:00:52 |
| User entered 'Yes (Y)' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685636

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User closed query 'Answer not p[resent in source. Please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 17:24:22 |
| DataPoint Verified. | | 13 Apr 2021 17:24:20 |
| Query 'Answer not p[resent in source. Please review and reconcile. ' answered with 'Confirmed diagnosis unavailable. PPD Reports returned "Out of Stability". Please see progress note in eSource.' (Site from CRA). | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:47:37 |
| User opened query 'Answer not p[resent in source. Please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 10 Feb 2021 19:01:19 |
| User entered 'No (N)' | | 27 Oct 2020 18:43:50 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 17:33:16 |
| User closed query 'Per DM CLR: RQ: Response noted, however, subject first felt this symptom on 20 AUG 2020 per eDiary. Please review and reconcile as appropriate. Otherwise, clarify.' (Site from DM). | | 06 Apr 2021 15:09:27 |
| Query 'Per DM CLR: RQ: Response noted, however, subject first felt this symptom on 20 AUG 2020 per eDiary. Please review and reconcile as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:35:09 |
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:35:01 |
| User entered '20 Aug 2020' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:35:01 |
| User opened query 'Per DM CLR: RQ: Response noted, however, subject first felt this symptom on 20 AUG 2020 per eDiary. Please review and reconcile as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 03 Apr 2021 11:06:48 |
| DataPoint Verified. | | 31 Mar 2021 20:57:29 |
| User closed query 'Start date does not match source. Please Review and reconcile' (Site from CRA). | | 31 Mar 2021 20:57:26 |
| Query 'Start date does not match source. Please Review and reconcile' answered with 'updated' (Site from CRA). | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:49:36 |
| User entered '24 Aug 2020' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:49:28 |
| User opened query 'Start date does not match source. Please Review and reconcile' (Site from CRA). | (b) (4), (b) (6) | 10 Feb 2021 19:01:57 |



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**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| 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 20AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4), (b) (6) | 25 Nov 2020 14:59:10 |
| Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 20AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated' (Site from DM). | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:48:29 |
| User entered '20 Aug 2020' reason for change: Data Entry Error | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:48:20 |
| 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 20AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:20:48 |
| User entered '24 Aug 2020' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685639

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 10:07:30 |
| Query 'Data is required. Please provide.' answered with 'unknown' (Site from System). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:36:00 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Apr 2021 20:35:01 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 29 Mar 2021 17:49:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:06 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 25 Nov 2020 14:57:13 |
| Query 'Data is required. Please provide.' answered with 'unknown' (Site from System). | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:48:34 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 24 Nov 2020 20:48:20 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:43:50 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 27 Oct 2020 18:43:50 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:08 |
| User entered 'No (N)' | | 27 Oct 2020 18:43:50 |



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**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:10 |
| User entered '30 Sep 2020' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685643

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 06 Apr 2021 10:07:32 |
| Query 'Data is required. Please provide.' answered with 'unknown' (Site from System). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:36:07 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Apr 2021 20:35:01 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 29 Mar 2021 17:49:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:12 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 25 Nov 2020 14:57:16 |
| Query 'Data is required. Please provide.' answered with 'unknown' (Site from System). | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:48:36 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 24 Nov 2020 20:48:20 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:43:50 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 27 Oct 2020 18:43:50 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:15 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685646

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:17 |
| User entered 'No (N)' | | 27 Oct 2020 18:43:50 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:20 |
| User entered '0' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685648

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:22 |
| User entered '0' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685649

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:25 |
| User entered '0' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685650

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:27 |
| User entered empty. | | 27 Oct 2020 18:43:50 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:29 |
| User entered empty. | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685652

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:34 |
| User entered empty. | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685653

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:43 |
| User entered empty. | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685654

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:50 |
| User entered '0' | | 27 Oct 2020 18:43:50 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:53 |
| User entered '0' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685656

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:02:55 |
| User entered '0' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685657

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:03:03 |
| User entered 'Related (RELATED)' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685658

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:03:05 |
| User entered 'Not Related (NOT RELATED)' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685659

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| User closed query 'Per CDM: Response noted 'Per PI AE is primary reason for dosing discontinuation'. Please review/update 'Dosing Discontinuation e CRF' as per your response else clarify. Thank you' (Site from DM). | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 14:04:36 |
| Query 'Per CDM: Response noted 'Per PI AE is primary reason for dosing discontinuation'. Please review/update 'Dosing Discontinuation e CRF' as per your response else clarify. Thank you' answered with 'updated' (Site from DM). | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:49:50 |
| User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 12 Feb 2021 11:41:46 |
| User opened query 'Per CDM: Response noted 'Per P AE is primary reason for dosing discontinuation'. Please review/update 'Dosing Discontinuation e CRF' as per your response else clarify. Thank you' (Site from DM). | | 11 Feb 2021 12:53:26 |
| DataPoint Verified. | | 10 Feb 2021 19:03:37 |
| User closed query 'Per DM CLR - RQ: Site's response noted. However, Dosing discontinuation is still not completed. Review and update. Else, clarify. ' (Site from DM). | | 09 Feb 2021 11:10:00 |
| Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Per PI AE is primary reason for dosing discontinuation' (Site from System). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:44:15 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Query 'Per DM CLR - RQ: Site's response noted. However, Dosing discontinuation is still not completed. Review and update. Else, clarify.<br />' answered with 'Please review dosing discontinuation form, was completed' (Site from DM). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:43:40 |
| User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System). | System | 12 Jan 2021 22:55:59 |
| User opened query 'Per DM CLR - RQ: Site's response noted. However, Dosing discontinuation is still not completed. Review and update. Else, clarify. ' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 06:04:43 |
| User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM). | | 25 Nov 2020 15:01:43 |
| Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' answered with 'Subject declined 2nd dose of the vaccination due to AE. ' (Site from DM). | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:44:25 |
| User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:20:35 |
| User closed query 'Per CDM: Action taken = Investigational Product Withdrawn for AE #(3) OCCIPATAL HEADACHE and #(4) FATIGUE however, only ONE event should be recorded as IP Withdrawn due to this AE? Please review and update accordingly else, clarify further.' (Site from DM). | | 23 Nov 2020 15:36:13 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Query 'Per CDM: Action taken = Investigational Product Withdrawn for AE #(3) OCCIPATAL HEADACHE and #(4) FATIGUE however, only ONE event should be recorded as IP Withdrawn due to this AE? Please review and update accordingly else, clarify further.' answered with 'Updated' (Site from DM). | Nathan Cortez (b) (4) | 06 Nov 2020 16:42:24 |
| User opened query 'Per CDM: Action taken = Investigational Product Withdrawn for AE #(3) OCCIPATAL HEADACHE and #(4) FATIGUE however, only ONE event should be recorded as IP Withdrawn due to this AE? Please review and update accordingly else, clarify further.' (Site from DM). | (b) (4), (b) (6) | 05 Nov 2020 22:19:59 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 27 Oct 2020 18:44:03 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 27 Oct 2020 18:44:03 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error | (b) (4), (b) (6) | 27 Oct 2020 18:44:03 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 27 Oct 2020 18:43:50 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:43:50 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:03:40 |
| User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #16 recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM). | | 25 Nov 2020 14:58:34 |
| Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #16 recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM). | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:46:38 |
| User entered '0' reason for change: Data Entry Error | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:46:30 |
| User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #16 recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:20:58 |
| User entered '1' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685663

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 19:03:42 |
| User entered '1' reason for change: Data Entry Error | Kevin Martinez (b) (4) | 24 Nov 2020 20:46:30 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685664

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:03:43 |
| User entered '0' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685665

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:03:45 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685666

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:03:47 |
| User entered empty. | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685667

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 19:03:49 |
| User entered empty. | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685668

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 27 Oct 2020 18:43:50 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | | 27 Oct 2020 18:43:50 |



FDA-CBER-2022-1614-1685670

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:59 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685671

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685672

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 19:03:59 |
| 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) (b) (4) | 27 Oct 2020 18:48:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Oct 2020 18:48:25 |
| Data point term sent to Coder | System | 27 Oct 2020 18:47:35 |
| User entered 'Fatigue' | (b) (4), (b) (6) | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685673

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:18 |
| User entered 'No (N)' | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685674

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:20 |
| User entered 'Yes (Y)' | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685675

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 17:24:03 |
| User closed query 'Answer not present in source. Please review and reconcile.' (Site from CRA). | | 13 Apr 2021 17:24:01 |
| Query 'Answer not present in source. Please review and reconcile.' answered with 'Confirmed diagnosis unavailable. PPD Reports returned "Out of Stability". Please see progress note in eSource.' (Site from CRA). | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:47:24 |
| User opened query 'Answer not present in source. Please review and reconcile.' (Site from CRA). | (b) (4), (b) (6) | 10 Feb 2021 19:04:36 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 27 Oct 2020 18:47:38 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 27 Oct 2020 18:47:38 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 27 Oct 2020 18:47:38 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 27 Oct 2020 18:47:28 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685676

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:39 |
| 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 20AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | | 25 Nov 2020 15:02:10 |
| Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 20AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated' (Site from DM). | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:49:20 |
| User entered '20 Aug 2020' reason for change: Data Entry Error | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:49:10 |
| 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 20AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:21:14 |
| User entered '24 Aug 2020' | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685677

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:41 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 25 Nov 2020 15:01:59 |
| Query 'Data is required. Please provide.' answered with 'unknown' (Site from System). | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:49:22 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 24 Nov 2020 20:49:10 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685678

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | | 27 Oct 2020 18:47:28 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:43 |
| User entered 'No (N)' | | 27 Oct 2020 18:47:28 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:45 |
| User entered '21 Sep 2020' | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685681

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:47 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 25 Nov 2020 15:02:03 |
| Query 'Data is required. Please provide.' answered with 'unknown' (Site from System). | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:49:31 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 24 Nov 2020 20:49:10 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:47:28 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 27 Oct 2020 18:47:28 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:50 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685684

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:52 |
| User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System). | System | 27 Oct 2020 18:50:40 |
| User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System). | System | 27 Oct 2020 18:50:12 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 27 Oct 2020 18:50:12 |
| User entered 'Yes (Y)' | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685685

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:53 |
| User entered '0' | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685686

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:55 |
| User entered '0' | | 27 Oct 2020 18:47:28 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:56 |
| User entered '0' | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685688

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:58 |
| User entered empty. | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685689

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:04:59 |
| User entered empty. | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685690

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:05:03 |
| User entered empty. | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685691

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:05:19 |
| User entered empty. | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685692

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:05:21 |
| User entered '0' | | 27 Oct 2020 18:47:28 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:05:23 |
| User entered '0' | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685694

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:05:24 |
| User entered '0' reason for change: Data Entry Error | | 27 Oct 2020 18:50:40 |
| User entered '1' | | 27 Oct 2020 18:47:28 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:05:31 |
| User entered 'Related (RELATED)' | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685696

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:05:33 |
| User entered 'Not Related (NOT RELATED)' | | 27 Oct 2020 18:47:28 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:05:34 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 06 Nov 2020 16:42:09 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' | (b) (4), (b) (6) | 27 Oct 2020 18:47:28 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:05:36 |
| User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #16 recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM). | | 11 Dec 2020 07:54:29 |
| Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #16 recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM). | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:50:14 |
| User entered '0' reason for change: Data Entry Error | Kevin Martinez (b) (4) (b) (4) | 24 Nov 2020 20:49:43 |
| User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #16 recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:21:24 |
| User entered '1' | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685699

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 19:05:38 |
| User entered '1' reason for change: Data Entry Error | Kevin Martinez (b) (4) | 24 Nov 2020 20:49:43 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685700

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:05:41 |
| User entered '0' | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685701

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:05:43 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | | 27 Oct 2020 18:47:28 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:05:45 |
| User entered empty. | | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685703

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 19:05:47 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 27 Oct 2020 18:50:12 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System). | System | 27 Oct 2020 18:50:12 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 27 Oct 2020 18:47:28 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685704

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 27 Oct 2020 18:50:12 |
| User entered '1' | System | 27 Oct 2020 18:47:28 |



FDA-CBER-2022-1614-1685705

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 27 Oct 2020 18:47:28 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (4)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:20 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685707

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685708

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| 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) (b) (4) | 05 Apr 2021 20:32:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Apr 2021 20:32:45 |
| Data point term sent to Coder | System | 05 Apr 2021 20:31:17 |
| User entered 'Abdominal Pain' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685709

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685711

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685712

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered '24 Nov 2020' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685713

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685714

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 05 Apr 2021 20:30:18 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered '16 Dec 2020' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685717

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685719

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685720

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685724

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685725

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685726

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685727

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685728

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685729

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685730

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685732

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685733

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered 'None (NONE)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered '1' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685736

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685737

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685738

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685739

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 17:57:16 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685740

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685741

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 05 Apr 2021 20:30:18 |



FDA-CBER-2022-1614-1685742

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (5)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:41:47 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685743

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685744

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:06 |
| 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) (b) (4) | 21 Apr 2021 19:56:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Apr 2021 19:56:48 |
| 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) (b) (4) | 21 Apr 2021 19:54:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Apr 2021 19:54:50 |
| Data point term sent to Coder | System | 21 Apr 2021 18:27:39 |
| User entered 'HEADACHE - REACTOGENICITY' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 18:26:46 |
| Data point term sent to Coder | | 21 Apr 2021 18:26:38 |
| User entered 'HEADACHE' reason for change: Data Entry Error | | 21 Apr 2021 18:25:53 |
| Data point term sent to Coder | | 21 Apr 2021 18:25:37 |
| Coding entries removed. | | 21 Apr 2021 18:25:27 |
| User entered 'HEADACHE - Reactogenicity' reason for change: Data Entry Error | | 21 Apr 2021 18:25:27 |
| 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) (b) (4) | 21 Apr 2021 16:58:03 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Apr 2021 16:58:03 |
| Data point term sent to Coder | System | 21 Apr 2021 16:45:55 |
| User entered 'Headache' | (b) (4), (b) (6) | 21 Apr 2021 16:45:01 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:08 |
| User entered 'No (N)' | | 21 Apr 2021 16:45:01 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:09 |
| User entered 'Yes (Y)' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685747

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Questions/Answer Missing in source. Please provide.' (Site from CRA). | | 23 Apr 2021 19:31:45 |
| DataPoint Verified. | | 23 Apr 2021 19:31:43 |
| Query 'Questions/Answer Missing in source. Please provide.' answered with 'source updated ' (Site from CRA). | Antonio Gutierrez (b) (4) (b) (4) | 23 Apr 2021 18:51:04 |
| User opened query 'Questions/Answer Missing in source. Please provide.' (Site from CRA). | (b) (4), (b) (6) | 22 Apr 2021 21:21:17 |
| DataPoint Un-verified. | | 22 Apr 2021 21:21:13 |
| DataPoint Verified. | | 22 Apr 2021 21:18:24 |
| User entered 'No (N)' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685748

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:27 |
| User entered '20 Aug 2020' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685749

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:28 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 22 Apr 2021 10:57:33 |
| Query 'Data is required. Please provide.' answered with 'Start time unknown' (Site from System). | | 21 Apr 2021 16:45:13 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 21 Apr 2021 16:45:01 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685750

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Apr 2021 16:45:01 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:32 |
| User entered 'No (N)' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685752

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 21:18:33 |
| User entered '27 Aug 2020' | (b) (4), (b) (6) | 21 Apr 2021 16:45:01 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:35 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 22 Apr 2021 10:57:35 |
| Query 'Data is required. Please provide.' answered with 'End time unknown' (Site from System). | | 21 Apr 2021 16:45:17 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 21 Apr 2021 16:45:01 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685754

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685755

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:43 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | | 21 Apr 2021 16:45:01 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:45 |
| User entered 'No (N)' | | 21 Apr 2021 16:45:01 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:49 |
| User entered '0' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685758

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:50 |
| User entered '0' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685759

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:53 |
| User entered '0' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685760

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:55 |
| User entered empty. | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685761

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:57 |
| User entered empty. | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685762

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:58 |
| User entered empty. | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685763

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:18:59 |
| User entered empty. | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685764

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:19:00 |
| User entered '0' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685765

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:19:02 |
| User entered '0' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685766

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:19:03 |
| User entered '0' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685767

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' (Site from DM). | | 26 Apr 2021 09:26:31 |
| DataPoint Verified. | | 23 Apr 2021 19:31:52 |
| Query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' answered by data change (Site from DM). | System | 23 Apr 2021 18:47:48 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:47:48 |
| User opened query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' (Site from DM). | (b) (4), (b) (6) | 22 Apr 2021 10:57:51 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 22 Apr 2021 10:57:42 |
| Query 'Data is required. Please complete.' answered with 'Pending doctor review' (Site from System). | | 21 Apr 2021 16:45:23 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 16:45:01 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685768

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' (Site from DM). | | 26 Apr 2021 09:26:33 |
| DataPoint Verified. | | 23 Apr 2021 19:31:54 |
| Query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' answered by data change (Site from DM). | System | 23 Apr 2021 18:47:48 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:47:48 |
| User opened query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' (Site from DM). | (b) (4), (b) (6) | 22 Apr 2021 10:58:01 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 22 Apr 2021 10:57:44 |
| Query 'Data is required. Please complete.' answered with 'Pending doctor review.' (Site from System). | | 21 Apr 2021 16:45:29 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 16:45:01 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685769

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:19:13 |
| User entered 'None (NONE)' | | 21 Apr 2021 16:45:01 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:29:38 |
| User entered '1' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:51:47 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 22 Apr 2021 21:19:52 |
| DataPoint Verified. | | 22 Apr 2021 21:19:21 |
| User entered '0' | | 21 Apr 2021 16:45:01 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Per source, "Other Action taken" is "none". Please review and reconcile. ' (Site from CRA). | | 23 Apr 2021 19:29:40 |
| DataPoint Verified. | | 23 Apr 2021 19:29:37 |
| Query 'Per source, "Other Action taken" is "none". Please review and reconcile. ' answered with 'updated' (Site from CRA). | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:51:55 |
| User entered '0' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:51:47 |
| User opened query 'Per source, "Other Action taken" is "none". Please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 22 Apr 2021 21:19:53 |
| User entered '1' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685772

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:19:55 |
| User entered '0' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685773

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:19:57 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685774

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:20:00 |
| User entered empty. | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685775

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:20:07 |
| User entered 'Since SAR occurred beyond 7 days post dose, this is now recorded as AE.' | | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685776

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685777

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 21 Apr 2021 16:45:01 |



FDA-CBER-2022-1614-1685778

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (6)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:16 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685779

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685780

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:20:20 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Aching joints - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Apr 2021 06:43:56 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Apr 2021 06:43:56 |
| Data point term sent to Coder | System | 21 Apr 2021 18:27:39 |
| User entered 'JOINT ACHES IN SEVERAL JOINTS - REACTOGENICITY' | (b) (4), (b) (6) | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685781

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:21:28 |
| User entered 'No (N)' | | 21 Apr 2021 18:27:19 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:20:23 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:29:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Apr 2021 18:29:32 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 18:29:32 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:28:02 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 18:28:02 |
| User entered 'Yes (Y)' | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685783

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Questions/Answer Missing in source. Please provide.' (Site from CRA). | | 23 Apr 2021 20:19:23 |
| DataPoint Verified. | | 23 Apr 2021 20:19:22 |
| Query 'Questions/Answer Missing in source. Please provide.' answered with 'source updated ' (Site from CRA). | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:52:11 |
| User opened query 'Questions/Answer Missing in source. Please provide.' (Site from CRA). | (b) (4), (b) (6) | 22 Apr 2021 21:21:02 |
| User entered 'No (N)' | | 21 Apr 2021 18:27:19 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:21:43 |
| User entered '26 Aug 2020' | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685785

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:21:45 |
| User entered empty. | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685786

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Apr 2021 18:27:19 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:21:47 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:28:02 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Apr 2021 18:28:02 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 18:28:02 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:27:19 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685788

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:21:49 |
| User entered '27 Aug 2020' reason for change: Data Entry Error | | 21 Apr 2021 18:28:02 |
| User entered empty. | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685789

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:21:51 |
| User entered empty. | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685790

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Apr 2021 18:27:19 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:21:58 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:28:02 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Apr 2021 18:28:02 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 18:28:02 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:27:19 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685792

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:01 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:28:02 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Apr 2021 18:28:02 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 18:28:02 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:27:19 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685793

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:04 |
| User entered '0' | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685794

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:06 |
| User entered '0' | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685795

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:07 |
| User entered '0' | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685796

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:09 |
| User entered empty. | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685797

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:11 |
| User entered empty. | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685798

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:12 |
| User entered empty. | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685799

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:14 |
| User entered empty. | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685800

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:16 |
| User entered '0' | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685801

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:17 |
| User entered '0' | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685802

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:19 |
| User entered '0' | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685803

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| DataPoint Verified. | | 29 Apr 2021 16:47:49 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Per CDM: Response noted 'Pending data entry. Please update when data is available. Thank you.' (Site from DM). | | 26 Apr 2021 09:27:08 |
| Query 'Per CDM: Response noted 'Pending data entry. Please update when data is available. Thank you.' answered by data change (Site from DM). | System | 23 Apr 2021 18:52:45 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:52:45 |
| User opened query 'Per CDM: Response noted 'Pending data entry. Please update when data is available. Thank you.' (Site from DM). | (b) (4), (b) (6) | 22 Apr 2021 10:58:33 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 22 Apr 2021 10:58:15 |
| Query 'Data is required. Please complete.' answered with 'Pending data entry' (Site from System). | | 21 Apr 2021 18:28:30 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:27:19 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685804

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| DataPoint Verified. | | 29 Apr 2021 16:47:51 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Per CDM: Response noted 'Pending data entry'. Please update when data is available. Thank you.' (Site from DM). | | 26 Apr 2021 09:27:14 |
| Query 'Per CDM: Response noted 'Pending data entry'. Please update when data is available. Thank you.' answered by data change (Site from DM). | System | 23 Apr 2021 18:52:45 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:52:45 |
| User opened query 'Per CDM: Response noted 'Pending data entry'. Please update when data is available. Thank you.' (Site from DM). | (b) (4), (b) (6) | 22 Apr 2021 10:58:49 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 22 Apr 2021 10:58:16 |
| Query 'Data is required. Please complete.' answered with 'Pending data entry' (Site from System). | | 21 Apr 2021 18:28:37 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:27:19 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685805

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:24 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:28:02 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Apr 2021 18:28:02 |
| User entered 'None (NONE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 18:28:02 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:27:19 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:27:19 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:31 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | | 21 Apr 2021 18:28:02 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 18:28:02 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 21 Apr 2021 18:27:19 |
| User entered '0' | (b) (4), (b) (6) | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685807

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:33 |
| User entered '0' | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685808

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:35 |
| User entered '0' | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685809

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:37 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 21 Apr 2021 18:28:02 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Apr 2021 18:28:02 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 18:28:02 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:27:19 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685810

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:38 |
| User entered empty. | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685811

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:22:40 |
| User entered 'Since SAR occurred beyond 7 days post dose, this is now recorded as AE' reason for change: Data Entry Error | | 21 Apr 2021 18:28:15 |
| User entered empty. | | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685812

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 21 Apr 2021 18:28:02 |



FDA-CBER-2022-1614-1685813

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 21 Apr 2021 18:27:19 |



FDA-CBER-2022-1614-1685814

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (7)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:35 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685815

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685816

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:10 |
| 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) (b) (4) | 22 Apr 2021 08:34:59 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Apr 2021 08:34:59 |
| Data point term sent to Coder | System | 21 Apr 2021 18:30:42 |
| User entered 'MUSCLE ACHES ALL OVER BODY - REACTOGENICITY' | (b) (4), (b) (6) | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685817

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:12 |
| User entered 'No (N)' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685818

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:13 |
| User entered 'Yes (Y)' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685819

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Questions/Answer Missing in source. Please provide.' (Site from CRA). | | 23 Apr 2021 19:34:07 |
| DataPoint Verified. | | 23 Apr 2021 19:34:05 |
| Query 'Questions/Answer Missing in source. Please provide.' answered with 'source updated' (Site from CRA). | Antonio Gutierrez (b) (4) (b) (4) | 23 Apr 2021 18:53:01 |
| User opened query 'Questions/Answer Missing in source. Please provide.' (Site from CRA). | (b) (4), (b) (6) | 22 Apr 2021 21:23:04 |
| User entered 'No (N)' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685820

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:24 |
| DataPoint Un-verified. | | 22 Apr 2021 21:23:14 |
| DataPoint Verified. | | 22 Apr 2021 21:23:09 |
| User entered '24 Aug 2020' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685821

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:27 |
| User entered empty. | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685822

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Apr 2021 18:30:27 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:29 |
| User entered 'No (N)' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685824

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:31 |
| User entered '27 Aug 2020' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685825

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:32 |
| User entered empty. | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685826

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685827

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:33 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685828

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:35 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:30:34 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Apr 2021 18:30:34 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 18:30:34 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:30:27 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685829

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:37 |
| User entered '0' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685830

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:38 |
| User entered '0' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685831

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:40 |
| User entered '0' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685832

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:42 |
| User entered empty. | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685833

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:43 |
| User entered empty. | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685834

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:44 |
| User entered empty. | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685835

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:46 |
| User entered empty. | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685836

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:47 |
| User entered '0' | | 21 Apr 2021 18:30:27 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:49 |
| User entered '0' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685838

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:23:51 |
| User entered '0' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685839

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' (Site from DM). | | 26 Apr 2021 09:28:49 |
| DataPoint Verified. | | 23 Apr 2021 19:34:15 |
| Query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' answered by data change (Site from DM). | | 23 Apr 2021 18:53:42 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:53:42 |
| User opened query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' (Site from DM). | (b) (4), (b) (6) | 22 Apr 2021 10:59:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 22 Apr 2021 10:58:58 |
| Query 'Data is required. Please complete.' answered with 'Pending doctor review.' (Site from System). | | 21 Apr 2021 18:30:43 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:30:27 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685840

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' (Site from DM). | | 26 Apr 2021 09:28:59 |
| DataPoint Verified. | | 23 Apr 2021 19:34:13 |
| Query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' answered by data change (Site from DM). | System | 23 Apr 2021 18:53:42 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:53:42 |
| User opened query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' (Site from DM). | (b) (4), (b) (6) | 22 Apr 2021 10:59:22 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 22 Apr 2021 10:59:13 |
| Query 'Data is required. Please complete.' answered with 'Pending doctor review.' (Site from System). | | 21 Apr 2021 18:30:49 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:30:27 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685841

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:24:01 |
| User entered 'None (NONE)' | | 21 Apr 2021 18:30:27 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:24:04 |
| User entered '1' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685843

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:24:05 |
| User entered '0' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685844

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:24:06 |
| User entered '0' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685845

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:24:07 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685846

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:24:09 |
| User entered empty. | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685847

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:24:10 |
| User entered 'Since SAR occurred beyond 7 days post dose, this is now recorded as AE' | | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685848

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 21 Apr 2021 18:30:34 |



FDA-CBER-2022-1614-1685849

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 21 Apr 2021 18:30:27 |



FDA-CBER-2022-1614-1685850

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (8)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:50 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685851

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685852

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:22 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 23 Apr 2021 19:03:13 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 23 Apr 2021 19:03:13 |
| Data point term sent to Coder | System | 23 Apr 2021 19:02:16 |
| User closed query 'DM-Coding: For coding purposes, Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. ' (Site from System). | System | 23 Apr 2021 19:01:41 |
| Query 'DM-Coding: For coding purposes, Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. ' answered with 'split into two events' (Site from System). | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:01:41 |
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:01:18 |
| User entered 'NAUSEA - REACTOGENICITY' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:01:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 21:24:25 |
| User opened query 'DM-Coding: For coding purposes, Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. ' (Site from System). | Coder Import (b) (4) (b) (4) | 22 Apr 2021 08:39:44 |
| Data point term sent to Coder | System | 21 Apr 2021 18:32:43 |
| User entered 'NAUSEA AND VOMITTING - REACTOGENICITY' | (b) (4), (b) (6) | 21 Apr 2021 18:31:48 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:24:23 |
| User entered 'No (N)' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685854

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:24:30 |
| User entered 'Yes (Y)' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685855

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:25:44 |
| User entered 'No (N)' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685856

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:25:45 |
| User entered '26 Aug 2020' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685857

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:25:47 |
| User entered empty. | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685858

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Apr 2021 18:31:48 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:25:49 |
| User entered 'No (N)' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685860

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:25:50 |
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). | System | 21 Apr 2021 18:32:03 |
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). | System | 21 Apr 2021 18:32:03 |
| User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System). | System | 21 Apr 2021 18:32:03 |
| User entered '27 Aug 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 18:32:03 |
| User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). | System | 21 Apr 2021 18:31:48 |
| User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System). | System | 21 Apr 2021 18:31:48 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685861

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:25:51 |
| User entered empty. | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685862

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Apr 2021 18:31:48 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:25:55 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685864

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:26:57 |
| User entered 'No (N)' | | 21 Apr 2021 18:31:48 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:28:03 |
| User entered '0' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685866

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:28:06 |
| User entered '0' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685867

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:28:08 |
| User entered '0' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685868

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:28:09 |
| User entered empty. | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685869

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:28:11 |
| User entered empty. | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685870

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:28:13 |
| User entered empty. | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685871

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:28:15 |
| User entered empty. | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685872

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:28:18 |
| User entered '0' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685873

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:28:20 |
| User entered '0' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685874

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:28:22 |
| User entered '0' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685875

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' (Site from DM). | | 26 Apr 2021 09:31:30 |
| DataPoint Verified. | | 23 Apr 2021 19:32:29 |
| Query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' answered by data change (Site from DM). | | 23 Apr 2021 18:54:14 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:54:14 |
| User opened query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' (Site from DM). | (b) (4), (b) (6) | 22 Apr 2021 10:59:37 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 22 Apr 2021 10:59:31 |
| Query 'Data is required. Please complete.' answered with 'Pending doctor review.' (Site from System). | | 21 Apr 2021 18:32:13 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:31:48 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685876

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' (Site from DM). | | 26 Apr 2021 09:32:39 |
| DataPoint Verified. | | 23 Apr 2021 19:32:31 |
| Query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' answered by data change (Site from DM). | | 23 Apr 2021 18:54:14 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:54:14 |
| User opened query 'Per CDM: Response noted 'Pending doctor review'. Please update when data is available. Thank you.' (Site from DM). | (b) (4), (b) (6) | 22 Apr 2021 10:59:47 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 22 Apr 2021 10:59:40 |
| Query 'Data is required. Please complete.' answered with 'Pending doctor review' (Site from System). | | 21 Apr 2021 18:32:23 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Apr 2021 18:31:48 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685877

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:27:02 |
| User entered 'None (NONE)' | | 21 Apr 2021 18:31:48 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:27:05 |
| User entered '1' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685879

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:27:06 |
| User entered '0' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685880

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:27:08 |
| User entered '0' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685881

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:27:10 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685882

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:27:11 |
| User entered empty. | | 21 Apr 2021 18:31:48 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 22 Apr 2021 21:27:13 |
| User entered 'Since SAR occurred beyond 7 days post dose, this is now recorded as AE' | | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685884

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685885

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 21 Apr 2021 18:31:48 |



FDA-CBER-2022-1614-1685886

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (9)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:43:04 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685887

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685888

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| 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) (b) (4) | 23 Apr 2021 19:06:02 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 23 Apr 2021 19:06:02 |
| Data point term sent to Coder | System | 23 Apr 2021 19:05:18 |
| User entered 'Vomiting - REACTOGENICITY' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685889

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685890

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered '26 Aug 2020' | Antonio Gutierrez (b) (4) (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685893

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered empty. | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685894

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 23 Apr 2021 19:04:31 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685896

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered '27 Aug 2020' | Antonio Gutierrez (b) (4) (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685897

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered empty. | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685898

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 23 Apr 2021 19:04:31 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685900

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685901

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered '0' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685902

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered '0' | Antonio Gutierrez (b) (4) (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685903

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered '0' | Antonio Gutierrez (b) (4) (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685904

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered empty. | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685905

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered empty. | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685906

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered empty. | Antonio Gutierrez (b) (4) (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685907

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered empty. | Antonio Gutierrez (b) (4) (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685908

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered '0' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685909

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered '0' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685910

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered '0' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685911

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered 'Related (RELATED)' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685912

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685913

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered 'None (NONE)' | Antonio Gutierrez (b) (4) (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685914

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered '1' | Antonio Gutierrez (b) (4) (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685915

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered '0' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685916

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered '0' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685917

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685918

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered empty. | Antonio Gutierrez (b) (4) (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685919

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 28 Apr 2021 13:37:32 |
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 23 Apr 2021 19:32:51 |
| User entered empty. | Antonio Gutierrez (b) (4) | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685920

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 23 Apr 2021 19:04:31 |



FDA-CBER-2022-1614-1685921

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |
| User entered '0' | System | 23 Apr 2021 19:04:31 |

**US3292241**
**Folder: Adverse Events**
**Form: Adverse Events (10)**
**Generated On: 11 Aug 2021 22:21:07**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 11:42:03 |
| Data hard unlocked. | | 29 Apr 2021 08:23:23 |
| Data hard locked. | | 26 Apr 2021 18:46:52 |



FDA-CBER-2022-1614-1685923

**US3292241**

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

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

**Generated On: 11 Aug 2021 22:21:07**

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

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User closed query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' (Site from DM). | (b) (4), (b) (6) | 16 Apr 2021 14:05:17 |
| DataPoint Verified. | | 13 Apr 2021 17:09:15 |
| User closed query 'Please add com meds Amox/Clav, Metronizadole, and moderna Vaccine to EDC.' (Site from CRA). | | 13 Apr 2021 17:09:14 |
| Query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' answered with 'this was added' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 13 Apr 2021 17:08:38 |
| User opened query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 09:08:16 |
| Query 'Please add com meds Amox/Clav, Metronizadole, and moderna Vaccine to EDC.' answered with 'done' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:35 |
| User opened query 'Please add com meds Amox/Clav, Metronizadole, and moderna Vaccine to EDC.' (Site from CRA). | (b) (4), (b) (6) | 10 Feb 2021 19:15:11 |
| User closed query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on Dairy dose 1 day 2, day 6, day 7, day 8 and day 9 Subject states he took Tylenol (500 mg) for Headache and body-aches , and temperature, Kindly update Tylenol in the concomitant medication page. ' (Site from DM). | | 30 Nov 2020 10:42:52 |

**US3292241**

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

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

**Generated On: 11 Aug 2021 22:21:07**

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

| Audit | User | Time (GMT) |
|---|---|---|
| Query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on Dairy dose 1 day 2, day 6, day 7, day 8 and day 9 Subject states he took Tylenol (500 mg) for Headache and body-aches , and temperature, Kindly update Tylenol in the concomitant medication page. ' answered with 'updated' (Site from DM). | Victoria Hernandez (b) (4) (b) (4) | 11 Nov 2020 15:07:40 |
| User opened query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on Dairy dose 1 day 2, day 6, day 7, day 8 and day 9 Subject states he took Tylenol (500 mg) for Headache and body-aches , and temperature, Kindly update Tylenol in the concomitant medication page. ' (Site from DM). | (b) (4), (b) (6) | 02 Nov 2020 10:33:26 |
| User closed query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on day 2, day 6, day 7, day 8 and day 9 Subject states he took Tylenol (500 mg) for Headache and body-aches , and temperature, Kindly update Tylenol in the concomitant medication page. Thank you. ' (Site from DM). | | 02 Nov 2020 10:31:17 |
| Query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on day 2, day 6, day 7, day 8 and day 9 Subject states he took Tylenol (500 mg) for Headache and body-aches , and temperature, Kindly update Tylenol in the concomitant medication page. Thank you. ' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 20:55:06 |
| User opened query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on day 2, day 6, day 7, day 8 and day 9 Subject states he took Tylenol (500 mg) for Headache and body-aches , and temperature, Kindly update Tylenol in the concomitant medication page. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 01 Sep 2020 19:32:20 |
| Query 'Per CDM: Per the participant response, medication was taken to treat pain or fever Subject states he took Tylenol (500 mg) for Headache and body-aches , and temperature, Kindly update Tylenol in the concomitant medication page. Thank you. ' canceled (Site from DM). | | 01 Sep 2020 19:32:10 |

**US3292241**

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

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

**Generated On: 11 Aug 2021 22:21:07**

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

| Audit | User | Time (GMT) |
|---|---|---|
| User opened query 'Per CDM: Per the participant response, medication was taken to treat pain or fever Subject states he took Tylenol (500 mg) for Headache and body-aches , and temperature, Kindly update Tylenol in the concomitant medication page. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 01 Sep 2020 19:22:15 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:06:18 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:25 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:09:27 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:09:27 |
| Data point term sent to Coder | System | 21 Aug 2020 15:08:38 |
| User entered 'Multivitamin' | (b) (4), (b) (6) | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685927

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:27 |
| User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM). | | 25 Nov 2020 17:42:40 |
| Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' answered with 'updated-self evident' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 05 Nov 2020 19:20:55 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 05 Nov 2020 19:20:52 |
| User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given a a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM). | (b) (4), (b) (6) | 05 Nov 2020 16:38:22 |
| User entered 'No (N)' | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685928

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:28 |
| User entered 'Supplement' | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685929

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:32 |
| User entered '1' | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685930

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:36 |
| User entered 'tablet (TABLET)' | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685931

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:54 |
| User entered empty. | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685932

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:38 |
| User entered 'once daily (QD)' | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685933

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:55 |
| User entered empty. | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685934

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:40 |
| User entered 'Oral (ORAL)' | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685935

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:56 |
| User entered empty. | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685936

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:42 |
| User entered 'un UNK 1960' | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685937

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:57 |
| User entered '0' | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685938

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:44 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685939

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:00 |
| User entered empty. | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685940

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:06:47 |
| User entered 'No (N)' | | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685941

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685942

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685943

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '804 (804)' | System | 21 Aug 2020 15:07:50 |



FDA-CBER-2022-1614-1685944

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:07 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: QUERCETIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Sep 2020 07:33:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Sep 2020 07:33:49 |
| Data point term sent to Coder | System | 21 Aug 2020 15:09:40 |
| User entered 'Quercetin' | (b) (4), (b) (6) | 21 Aug 2020 15:08:46 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:09 |
| User entered 'No (N)' | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685946

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:11 |
| User entered 'Seasonal allergies' | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685947

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:12 |
| User entered '1' | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685948

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:14 |
| User entered 'tablet (TABLET)' | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685949

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:15 |
| User entered empty. | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685950

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:17 |
| User entered 'once daily (QD)' | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685951

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:18 |
| User entered empty. | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685952

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:20 |
| User entered 'Oral (ORAL)' | | 21 Aug 2020 15:08:46 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:21 |
| User entered empty. | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685954

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:23 |
| User entered 'un UNK 2000' | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685955

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:24 |
| User entered '0' | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685956

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:29 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685957

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:30 |
| User entered empty. | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685958

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:32 |
| User entered 'No (N)' | | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685959

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685960

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685961

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '804 (804)' | System | 21 Aug 2020 15:08:46 |



FDA-CBER-2022-1614-1685962

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:35 |
| 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) (b) (4) | 21 Aug 2020 15:11:16 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:11:16 |
| Data point term sent to Coder | System | 21 Aug 2020 15:10:41 |
| User entered 'Melatonin' | (b) (4), (b) (6) | 21 Aug 2020 15:09:43 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:41 |
| User entered 'No (N)' | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685964

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:42 |
| User entered 'Insomnia' | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685965

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 19:07:49 |
| User entered '3' | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685966

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:52 |
| User entered 'mg (mg)' | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685967

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:53 |
| User entered empty. | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685968

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:55 |
| User entered 'as needed (PRN)' | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685969

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:56 |
| User entered empty. | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685970

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:07:58 |
| User entered 'Oral (ORAL)' | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685971

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:08:12 |
| User entered empty. | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685972

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:08:13 |
| User entered 'un UNK 2015' | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685973

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:08:16 |
| User entered '0' | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685974

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:08:18 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685975

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:08:20 |
| User entered empty. | | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685976

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:08:21 |
| User entered 'No (N)' | | 21 Aug 2020 15:09:43 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685978

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685979

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:09:43 |



FDA-CBER-2022-1614-1685980

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:12:50 |
| User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CARMELLOSE SODIUM, PRODUCTSYNONYM: REFRESH PLUS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 08 Sep 2020 11:02:45 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 08 Sep 2020 11:02:45 |
| Data point term sent to Coder | System | 21 Aug 2020 15:11:46 |
| User entered 'Refresh Plus eye drops' | (b) (4), (b) (6) | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685981

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:12:51 |
| User entered 'No (N)' | | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685982

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:12:53 |
| User entered 'Dry eyes' | | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685983

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:12:54 |
| User entered '2' | | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685984

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:12:56 |
| User entered 'Other (OTHER)' | | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685985

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:12:57 |
| User entered 'drops' | | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685986

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:12:58 |
| User entered 'as needed (PRN)' | | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685987

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:11 |
| User entered empty. | | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685988

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:01 |
| User entered 'Intraocular (INTRAOCULAR)' | | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685989

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:12 |
| User entered empty. | | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685990

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:03 |
| User entered 'un UNK 2000' | | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685991

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:22 |
| DataPoint Un-verified. | | 26 Jan 2021 19:13:19 |
| DataPoint Verified. | | 26 Jan 2021 19:13:18 |
| User entered '0' | | 21 Aug 2020 15:11:18 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:05 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685993

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:21 |
| User entered empty. | | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685994

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:07 |
| User entered 'No (N)' | | 21 Aug 2020 15:11:18 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685996

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685997

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:11:18 |



FDA-CBER-2022-1614-1685998

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:33 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: FIBRE, DIETARY - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 04 Sep 2020 18:53:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 04 Sep 2020 18:53:37 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: POLYCARBOPHIL CALCIUM, PRODUCTSYNONYM: FIBER - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:13:20 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:13:20 |
| Data point term sent to Coder | System | 21 Aug 2020 15:12:48 |
| User entered 'Fiber' | (b) (4), (b) (6) | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1685999

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:35 |
| User entered 'No (N)' | | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686000

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:37 |
| User entered 'Constipation' | | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686001

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:42 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). | | 13 Nov 2020 22:49:16 |
| Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'unknown per patient' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:55:07 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, 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) | 18 Sep 2020 11:36:27 |
| User entered '1' | | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686002

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:44 |
| User entered 'tablet (TABLET)' | | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686003

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:45 |
| User entered empty. | | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686004

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:47 |
| User entered 'as needed (PRN)' | | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686005

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:52 |
| User entered empty. | | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686006

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:51 |
| User entered 'Oral (ORAL)' | | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686007

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:53 |
| User entered empty. | | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686008

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:55 |
| User entered 'un UNK 2000' | | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686009

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:56 |
| User entered '0' | | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686010

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:58 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686011

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:13:59 |
| User entered empty. | | 21 Aug 2020 15:12:13 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:00 |
| User entered 'No (N)' | | 21 Aug 2020 15:12:13 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686014

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686015

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:12:13 |



FDA-CBER-2022-1614-1686016

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:08 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: TELMISARTAN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:15:25 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:15:25 |
| Data point term sent to Coder | System | 21 Aug 2020 15:13:49 |
| User entered 'Telmisartan' | (b) (4), (b) (6) | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686017

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:09 |
| User entered 'No (N)' | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686018

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:12 |
| User entered 'Hypertension' | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686019

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:14 |
| User entered '5' | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686020

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:15 |
| User entered 'mg (mg)' | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686021

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:48 |
| User entered empty. | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686022

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:23 |
| User entered 'once daily (QD)' | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686023

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:50 |
| User entered empty. | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686024

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:29 |
| User entered 'Oral (ORAL)' | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686025

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:51 |
| User entered empty. | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686026

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:38 |
| User entered 'un Jan 2020' | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686027

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:53 |
| User entered '0' | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686028

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:55 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686029

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:57 |
| User entered empty. | | 21 Aug 2020 15:13:04 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:14:59 |
| User entered 'No (N)' | | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686031

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686032

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686033

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '804 (804)' | System | 21 Aug 2020 15:13:04 |



FDA-CBER-2022-1614-1686034

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:15:40 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:15:25 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:15:25 |
| Data point term sent to Coder | System | 21 Aug 2020 15:14:52 |
| User entered 'Montelukast' | (b) (4), (b) (6) | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686035

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:15:45 |
| User entered 'No (N)' | | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686036

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:15:46 |
| User entered 'Seasonal allergies' | | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686037

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:15:48 |
| User entered '5' | | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686038

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:15:49 |
| User entered 'mg (mg)' | | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686039

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:15:51 |
| User entered empty. | | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686040

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:15:53 |
| User entered 'as needed (PRN)' | | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686041

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:15:55 |
| User entered empty. | | 21 Aug 2020 15:14:18 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:15:57 |
| User entered 'Oral (ORAL)' | | 21 Aug 2020 15:14:18 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:16:03 |
| User entered empty. | | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686044

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:16:08 |
| User entered 'un UNK 2017' | | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686045

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:16:10 |
| User entered '0' | | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686046

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:16:13 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686047

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:16:17 |
| User entered empty. | | 21 Aug 2020 15:14:18 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:16:21 |
| User entered 'No (N)' | | 21 Aug 2020 15:14:18 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686050

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686051

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:14:18 |



FDA-CBER-2022-1614-1686052

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:16:35 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: NASACORT - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Sep 2020 23:56:47 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Sep 2020 23:56:47 |
| Data point term sent to Coder | System | 21 Sep 2020 23:55:58 |
| Coding entries removed. | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:55:27 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: NASACORT - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:17:19 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:17:19 |
| Data point term sent to Coder | System | 21 Aug 2020 15:15:54 |
| User entered 'Nasacort' | (b) (4), (b) (6) | 21 Aug 2020 15:15:09 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:16:37 |
| User entered 'No (N)' | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686054

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:16:56 |
| User entered 'Seasonal allergies' | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686055

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:08:38 |
| User closed query 'Please confirm value with source and ypdate EDC accordingly.' (Site from CRA). | | 10 Feb 2021 19:08:37 |
| Query 'Please confirm value with source and ypdate EDC accordingly.' answered with 'Verified source. correct as is.' (Site from CRA). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:32:42 |
| User opened query 'Please confirm value with source and ypdate EDC accordingly.' (Site from CRA). | (b) (4), (b) (6) | 26 Jan 2021 19:18:10 |
| 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). | | 25 Nov 2020 17:43:06 |
| 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 'update' (Site from DM). | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 20:32:01 |
| User entered '220' reason for change: Data Entry Error | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 20:31:54 |
| 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). | (b) (4), (b) (6) | 22 Oct 2020 08:03:18 |
| User entered '48.75' | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686056

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:18:15 |
| User entered 'ug (ug)' reason for change: Data Entry Error | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 20:33:50 |
| User entered 'IU (IU)' reason for change: Data Entry Error | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 20:31:54 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 21 Aug 2020 15:15:09 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:18:36 |
| User entered empty. | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686058

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:17:36 |
| User entered 'as needed (PRN)' | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686059

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:18:19 |
| User entered empty. | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686060

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 19:18:18 |
| User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM). | | 07 Oct 2020 09:43:46 |
| Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'updated ' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:55:39 |
| User entered 'Nasal (NASAL)' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:55:27 |
| User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 18 Sep 2020 11:39:33 |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686061

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:18:21 |
| User entered empty. | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686062

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:18:28 |
| User entered 'un UNK 2010' | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686063

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:18:29 |
| User entered '0' | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686064

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:18:31 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686065

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:18:32 |
| User entered empty. | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686066

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:18:34 |
| User entered 'No (N)' | | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686067

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686068

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686069

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:15:09 |



FDA-CBER-2022-1614-1686070

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:18:50 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: THYROID, PRODUCTSYNONYM: NATURE THROID - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:17:21 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:17:21 |
| Data point term sent to Coder | System | 21 Aug 2020 15:16:59 |
| User entered 'Nature thyroid' | (b) (4), (b) (6) | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686071

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:19:06 |
| User entered 'No (N)' | | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686072

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:19:07 |
| User entered 'Hypothyroidism' | | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686073

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:08:52 |
| User closed query 'Please confirm value with source and update EDC accordingly' (Site from CRA). | | 10 Feb 2021 19:08:50 |
| Query 'Please confirm value with source and update EDC accordingly' answered with 'Value matches source, correct as is.' (Site from CRA). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:33:28 |
| User opened query 'Please confirm value with source and update EDC accordingly' (Site from CRA). | (b) (4), (b) (6) | 26 Jan 2021 19:20:27 |
| User entered '48.75' reason for change: Data Entry Error | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 20:47:57 |
| User entered '88' | (b) (4), (b) (6) | 21 Aug 2020 15:16:07 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:20:40 |
| User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM). | | 30 Nov 2020 16:02:21 |
| Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit.' answered with 'updated' (Site from DM). | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 20:48:04 |
| User entered 'mg (mg)' reason for change: Data Entry Error | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 20:47:57 |
| User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM). | (b) (4), (b) (6) | 22 Oct 2020 06:03:53 |
| User closed query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM). | | 07 Oct 2020 09:44:09 |
| Query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:56:30 |
| User entered 'ug (ug)' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:56:22 |

**US3292241**

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

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:21:07**

Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| User opened query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.<br />' (Site from DM). | (b) (4), (b) (6) | 18 Sep 2020 11:38:56 |
| User entered 'Other (OTHER)' | | 21 Aug 2020 15:16:07 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:20:48 |
| User entered empty; reason for change Data Entry Error | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:56:22 |
| User entered 'mcg' | (b) (4), (b) (6) | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686077

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:20:46 |
| User entered 'once daily (QD)' | | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686078

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:20:49 |
| User entered empty. | | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686079

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:20:50 |
| User entered 'Oral (ORAL)' | | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686080

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:20:52 |
| User entered empty. | | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686081

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:20:57 |
| User entered 'un UNK 2001' | | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686082

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:20:59 |
| User entered '0' | | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686083

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:21:00 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686084

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:21:02 |
| User entered empty. | | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686085

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:21:11 |
| User entered 'No (N)' | | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686086

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686087

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686088

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '804 (804)' | System | 21 Aug 2020 15:16:07 |



FDA-CBER-2022-1614-1686089

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:21:35 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:19:16 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:19:16 |
| Data point term sent to Coder | System | 21 Aug 2020 15:17:59 |
| User entered 'Zolpidem' | (b) (4), (b) (6) | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686090

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:21:36 |
| User entered 'No (N)' | | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686091

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:21:37 |
| User entered 'Insomnia' | | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686092

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:21:38 |
| User entered '5' | | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686093

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:21:39 |
| User entered 'mg (mg)' | | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686094

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:21:41 |
| User entered empty. | | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686095

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:21:47 |
| User entered 'as needed (PRN)' | | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686096

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:21:49 |
| User entered empty. | | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686097

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:22:00 |
| User entered 'Oral (ORAL)' | | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686098

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:22:25 |
| User entered empty. | | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686099

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:22:29 |
| User entered 'un UNK 2015' | | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686100

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:22:31 |
| User entered '0' | | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686101

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:23:28 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686102

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:23:30 |
| User entered empty. | | 21 Aug 2020 15:17:27 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:23:31 |
| User entered 'No (N)' | | 21 Aug 2020 15:17:27 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686105

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686106

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 15:17:27 |



FDA-CBER-2022-1614-1686107

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:24:32 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL, PRODUCTSYNONYM: ESTROGEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Aug 2020 13:20:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Aug 2020 13:20:41 |
| Data point term sent to Coder | System | 21 Aug 2020 15:19:01 |
| User entered 'Estrogen' | (b) (4), (b) (6) | 21 Aug 2020 15:18:56 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:24:34 |
| User entered 'No (N)' | | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686109

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:24:35 |
| User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' (Site from DM). | | 07 Oct 2020 09:44:45 |
| Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' answered with 'no underlying condition' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:57:25 |
| User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' (Site from DM). | (b) (4), (b) (6) | 18 Sep 2020 11:37:15 |
| User entered 'Hormone replacement' | | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686110

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:24:37 |
| User closed query ' Per DM CLR: Note, 2 mg/ml is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1 Application, etc). Update as appropriate.' (Site from DM). | | 07 Oct 2020 09:45:12 |
| Query ' Per DM CLR: Note, 2 mg/ml is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1 Application, etc). Update as appropriate.' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:59:48 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 21 Sep 2020 23:59:42 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Sep 2020 23:59:42 |
| User entered '1' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:59:42 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Sep 2020 23:59:16 |
| User entered empty; reason for change Data Entry Error | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:59:16 |
| User opened query ' Per DM CLR: Note, 2 mg/ml is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1 Application, etc). Update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 18 Sep 2020 11:37:27 |
| User entered '2' | | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686111

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:24:43 |
| User entered 'Other (OTHER)' | | 21 Aug 2020 15:18:56 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:01 |
| User entered 'application' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 21 Sep 2020 23:59:16 |
| User entered 'mg/mL' | (b) (4), (b) (6) | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686113

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:03 |
| User entered 'once daily (QD)' | | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686114

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:04 |
| User entered empty. | | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686115

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:11 |
| User entered 'Topical (TOPICAL)' | | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686116

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:14 |
| User entered empty. | | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686117

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:15 |
| User entered 'un UNK 2000' | | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686118

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 15:18:56 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:32 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686120

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:34 |
| User entered empty. | | 21 Aug 2020 15:18:56 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:35 |
| User entered 'No (N)' | | 21 Aug 2020 15:18:56 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686123

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686124

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '804 (804)' | System | 21 Aug 2020 15:18:56 |



FDA-CBER-2022-1614-1686125

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:42 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:21:20 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 15:21:20 |
| Data point term sent to Coder | System | 21 Aug 2020 15:20:02 |
| User entered 'Progesterone' | (b) (4), (b) (6) | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686126

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:44 |
| User entered 'No (N)' | | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686127

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:46 |
| User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 09:45:27 |
| Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' answered with 'no underlying condition' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 22 Sep 2020 00:00:07 |
| User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' (Site from DM). | (b) (4), (b) (6) | 18 Sep 2020 11:37:53 |
| User entered 'Hormone replacement' | | 21 Aug 2020 15:19:53 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:49 |
| User entered '100' | | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686129

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:50 |
| User entered 'mg (mg)' | | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686130

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:52 |
| User entered empty. | | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686131

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:53 |
| User entered 'once daily (QD)' | | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686132

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:55 |
| User entered empty. | | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686133

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:57 |
| User entered 'Oral (ORAL)' | | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686134

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:25:58 |
| User entered empty. | | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686135

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:02 |
| User entered 'un UNK 2000' | | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686136

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:04 |
| User entered '0' | | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686137

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:06 |
| User entered 'Yes (Y)' | | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686138

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:07 |
| User entered empty. | | 21 Aug 2020 15:19:53 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:09 |
| User entered 'No (N)' | | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686140

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686141

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686142

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '804 (804)' | System | 21 Aug 2020 15:19:53 |



FDA-CBER-2022-1614-1686143

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:28 |
| User closed query 'Per MM: "As needed" frequency is not considered as a stable dose, please confirm if the subject's dose is within allowable dose- for corticosteroids, it should be ≥ 20 mg/day of prednisone equivalent. ' (Site from DM). | | 13 Nov 2020 22:43:40 |
| Query 'Per MM: "As needed" frequency is not considered as a stable dose, please confirm if the subject's dose is within allowable dose- for corticosteroids, it should be ≥ 20 mg/day of prednisone equivalent. ' answered with 'this is what subject uses with medication' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 22 Sep 2020 00:00:40 |
| User opened query 'Per MM: "As needed" frequency is not considered as a stable dose, please confirm if the subject's dose is within allowable dose- for corticosteroids, it should be ≥ 20 mg/day of prednisone equivalent. ' (Site from DM). | (b) (4), (b) (6) | 17 Sep 2020 11:52:23 |
| 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: GLUCOCORTICOIDS, PRODUCT: PREDNISOLONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Aug 2020 11:26:42 |
| 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 Aug 2020 11:26:42 |
| Data point term sent to Coder | System | 21 Aug 2020 16:19:45 |
| User entered 'Prednisolone' | (b) (4), (b) (6) | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686144

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:31 |
| User entered 'No (N)' | | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686145

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:37 |
| User entered 'Asthma' | | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686146

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:41 |
| User entered '10' | | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686147

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:42 |
| User entered 'mg (mg)' | | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686148

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:44 |
| User entered empty. | | 21 Aug 2020 16:19:02 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:47 |
| User entered 'as needed (PRN)' | | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686150

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:26:52 |
| User entered empty. | | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686151

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:27:07 |
| User entered 'Oral (ORAL)' | | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686152

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:27:08 |
| User entered empty. | | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686153

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:27:10 |
| User entered 'un UNK 2015' | | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686154

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:27:12 |
| User entered '0' | | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686155

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Data not specified in con med log. Please review and reconcile. ' (Site from CRA). | | 19 Apr 2021 19:37:14 |
| DataPoint Verified. | | 19 Apr 2021 19:37:12 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| Query 'Data not specified in con med log. Please review and reconcile. ' answered with 'con med log updated' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:31:34 |
| User opened query 'Data not specified in con med log. Please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 10 Feb 2021 19:10:01 |
| DataPoint Un-verified. | | 10 Feb 2021 19:09:29 |
| DataPoint Verified. | | 26 Jan 2021 19:27:18 |
| User entered 'Yes (Y)' | | 21 Aug 2020 16:19:02 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:27:20 |
| User entered empty. | | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686157

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Jan 2021 19:27:26 |
| User entered 'No (N)' | | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686158

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686159

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686160

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Aug 2020 16:19:02 |



FDA-CBER-2022-1614-1686161

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:05 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 06 Apr 2021 07:24:04 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 06 Apr 2021 07:24:04 |
| Data point term sent to Coder | System | 05 Apr 2021 20:38:39 |
| Coding entries removed. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:38:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:10:14 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 09 Feb 2021 00:52:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 09 Feb 2021 00:52:52 |
| Data point term sent to Coder | System | 08 Feb 2021 19:45:54 |
| Coding entries removed. | Victoria Hernandez (b) (4) | 08 Feb 2021 19:45:22 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 27 Oct 2020 19:08:32 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 27 Oct 2020 19:08:32 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data point term sent to Coder | System | 27 Oct 2020 19:07:13 |
| User entered 'clindamycin' | (b) (4), (b) (6) | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686163

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:10:16 |
| User entered 'No (N)' | | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686164

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Pleas update indication in con med log' (Site from CRA). | | 19 Apr 2021 19:37:30 |
| DataPoint Verified. | | 19 Apr 2021 19:37:28 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'BILATERAL LYMPHADENITIS (Neck)' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:38:36 |
| Query 'Pleas update indication in con med log' answered with 'updated' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:33:09 |
| User opened query 'Pleas update indication in con med log' (Site from CRA). | (b) (4), (b) (6) | 10 Feb 2021 19:11:01 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM). | | 09 Feb 2021 10:47:23 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Changed AE Indication to properly document medication that was added to log' (Site from DM). | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:46:08 |
| User entered 'bilateral lymphadenitis' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 08 Feb 2021 19:45:22 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable detail to the AE eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 16 Jan 2021 20:38:13 |
| User entered 'TOOTH INFECTION' | | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686165

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:12 |
| User entered '150' | | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686166

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:14 |
| User entered 'mg (mg)' | | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686167

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:16 |
| User entered empty. | | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686168

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:18 |
| User entered 'as needed (PRN)' reason for change: Data Entry Error | Kevin Martinez (b) (4) (b) (4) | 04 Nov 2020 20:49:05 |
| User entered 'other (OTHER)' | (b) (4), (b) (6) | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686169

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:20 |
| User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System). | System | 04 Nov 2020 20:49:05 |
| User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System). | System | 27 Oct 2020 19:06:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Oct 2020 19:06:35 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:22 |
| User entered 'Oral (ORAL)' | | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686171

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:24 |
| User entered empty. | | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686172

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:27 |
| User entered '22 Sep 2020' | | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686173

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:29 |
| User entered '0' | | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686174

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:30 |
| User entered 'No (N)' | | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686175

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:32 |
| User entered '24 Sep 2020' | | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686176

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:33 |
| User entered 'No (N)' | | 27 Oct 2020 19:06:35 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686178

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686179

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 27 Oct 2020 19:06:35 |



FDA-CBER-2022-1614-1686180

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:44 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 29 Oct 2020 17:10:59 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 29 Oct 2020 17:10:59 |
| Data point term sent to Coder | System | 27 Oct 2020 19:08:15 |
| User entered 'INFLUENZA VACINE' | (b) (4), (b) (6) | 27 Oct 2020 19:08:09 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:46 |
| User entered 'Yes (Y)' | | 27 Oct 2020 19:08:09 |



FDA-CBER-2022-1614-1686182

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:47 |
| User entered 'PROPHYLAXIS' | | 27 Oct 2020 19:08:09 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:49 |
| User entered '1' | | 27 Oct 2020 19:08:09 |



FDA-CBER-2022-1614-1686184

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:51 |
| User entered 'Other (OTHER)' | | 27 Oct 2020 19:08:09 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:52 |
| User entered 'INJECTION' | | 27 Oct 2020 19:08:09 |



FDA-CBER-2022-1614-1686186

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:54 |
| User entered 'once (ONCE)' | | 27 Oct 2020 19:08:09 |



FDA-CBER-2022-1614-1686187

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:56 |
| User entered empty. | | 27 Oct 2020 19:08:09 |



FDA-CBER-2022-1614-1686188

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:57 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | | 27 Oct 2020 19:08:09 |



FDA-CBER-2022-1614-1686189

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:11:59 |
| User entered empty. | | 27 Oct 2020 19:08:09 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:00 |
| User entered '13 Oct 2020' | | 27 Oct 2020 19:08:09 |



FDA-CBER-2022-1614-1686191

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:02 |
| User entered '0' | | 27 Oct 2020 19:08:09 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:04 |
| User entered 'No (N)' | | 27 Oct 2020 19:08:09 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:06 |
| User entered '13 Oct 2020' | | 27 Oct 2020 19:08:09 |



FDA-CBER-2022-1614-1686194

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:08 |
| User entered 'No (N)' | | 27 Oct 2020 19:08:09 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 27 Oct 2020 19:08:09 |



FDA-CBER-2022-1614-1686196

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 27 Oct 2020 19:08:09 |



FDA-CBER-2022-1614-1686197

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 27 Oct 2020 19:08:09 |



FDA-CBER-2022-1614-1686198

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:20 |
| 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) (b) (4) | 05 Nov 2020 19:58:24 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 19:58:24 |
| Data point term sent to Coder | System | 05 Nov 2020 19:58:06 |
| User entered 'Tylenol' | (b) (4), (b) (6) | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686199

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:22 |
| User entered 'No (N)' | | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686200

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:24 |
| User entered 'Reactogenicity (HEADACHES,FATIGUE)' | | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686201

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:25 |
| User entered '500' | | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686202

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:29 |
| User entered 'mg (mg)' | | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686203

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | | 19 Apr 2021 19:37:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered empty. | (b) (4), (b) (6) | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686204

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:33 |
| User entered 'once daily (QD)' | | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686205

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:37 |
| User entered empty. | | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686206

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:41 |
| User entered 'Oral (ORAL)' | | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686207

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:55 |
| User entered empty. | | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686208

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:43 |
| User entered '20 Aug 2020' | | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686209

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:45 |
| User entered '0' | | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686210

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:49 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 05 Nov 2020 19:57:11 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 05 Nov 2020 19:57:11 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 05 Nov 2020 19:57:11 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 05 Nov 2020 19:57:05 |
| User entered empty. | (b) (4), (b) (6) | 05 Nov 2020 19:57:05 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:51 |
| User entered '27 Aug 2020' | | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686212

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:12:57 |
| User entered 'Yes (Y)' | | 05 Nov 2020 19:57:05 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686214

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686215

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '804 (804)' | System | 05 Nov 2020 19:57:05 |



FDA-CBER-2022-1614-1686216

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Apr 2021 12:06:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Apr 2021 12:06:46 |
| Data point term sent to Coder | System | 05 Apr 2021 20:26:11 |
| User entered 'Amox/Clav' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |



FDA-CBER-2022-1614-1686217

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |



FDA-CBER-2022-1614-1686218

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'Abdominal pain' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered '875/175' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |



FDA-CBER-2022-1614-1686220

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'mg (mg)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |



FDA-CBER-2022-1614-1686221

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |



FDA-CBER-2022-1614-1686222

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'twice daily (BID)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'Oral (ORAL)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered '27 Nov 2020' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |



FDA-CBER-2022-1614-1686227

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |



FDA-CBER-2022-1614-1686228

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered '4 Dec 2020' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |



FDA-CBER-2022-1614-1686230

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:20 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:26:11 |



FDA-CBER-2022-1614-1686231

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2' | System | 05 Apr 2021 20:26:11 |



FDA-CBER-2022-1614-1686232

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 05 Apr 2021 20:26:11 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (17)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '804 (804)' | System | 05 Apr 2021 20:26:11 |



FDA-CBER-2022-1614-1686234

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Apr 2021 12:31:59 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Apr 2021 12:31:59 |
| Data point term sent to Coder | System | 05 Apr 2021 20:27:12 |
| User entered 'Metronidazole' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |



FDA-CBER-2022-1614-1686236

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'Abdominal Pain' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered '300' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |



FDA-CBER-2022-1614-1686238

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'mg (mg)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |



FDA-CBER-2022-1614-1686239

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |



FDA-CBER-2022-1614-1686240

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'twice daily (BID)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'Oral (ORAL)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |



FDA-CBER-2022-1614-1686244

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered '27 Nov 2020' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered '4 Dec 2020' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |



FDA-CBER-2022-1614-1686248

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:27:06 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '2' | System | 05 Apr 2021 20:27:06 |



FDA-CBER-2022-1614-1686250

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '1' | System | 05 Apr 2021 20:27:06 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (18)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered '804 (804)' | System | 05 Apr 2021 20:27:06 |



FDA-CBER-2022-1614-1686252

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Apr 2021 12:32:55 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Apr 2021 12:32:55 |
| Data point term sent to Coder | System | 05 Apr 2021 20:29:15 |
| User entered 'Moderna Vaccine' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |



FDA-CBER-2022-1614-1686254

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'COVID-19 Vaccination' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |



FDA-CBER-2022-1614-1686255

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered '0.5' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |



FDA-CBER-2022-1614-1686256

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'mL (mL)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |



FDA-CBER-2022-1614-1686258

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'once (ONCE)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |



FDA-CBER-2022-1614-1686259

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |



FDA-CBER-2022-1614-1686260

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |



FDA-CBER-2022-1614-1686261

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered '24 Dec 2020' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |



FDA-CBER-2022-1614-1686264

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered '24 Dec 2020' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |



FDA-CBER-2022-1614-1686266

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 19:38:51 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:28:23 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 05 Apr 2021 20:28:23 |



FDA-CBER-2022-1614-1686268

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 05 Apr 2021 20:28:23 |



FDA-CBER-2022-1614-1686269

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (19)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 05 Apr 2021 20:28:23 |



FDA-CBER-2022-1614-1686270

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, PRODUCT: ANALGESICS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Apr 2021 14:30:12 |
| 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 Apr 2021 14:30:12 |
| Data point term sent to Coder | System | 23 Apr 2021 07:22:41 |
| User closed query 'DM-Coding: This trade name cannot be referred in the standard coding dictionary. Please enter correct trade name with its generic/active ingredient(s) in the drug name field to enable coding. Please make your changes to the reported term. ' (Site from System). | System | 23 Apr 2021 07:22:15 |
| Query 'DM-Coding: This trade name cannot be referred in the standard coding dictionary. Please enter correct trade name with its generic/active ingredient(s) in the drug name field to enable coding. Please make your changes to the reported term. ' answered with 'unknown' (Site from System). | Dawn Killian (b) (4) (b) (4) | 23 Apr 2021 07:22:15 |
| User opened query 'DM-Coding: This trade name cannot be referred in the standard coding dictionary. Please enter correct trade name with its generic/active ingredient(s) in the drug name field to enable coding. Please make your changes to the reported term. ' (Site from System). | Coder Import (b) (4) (b) (4) | 22 Apr 2021 08:41:55 |
| Data point term sent to Coder | System | 21 Apr 2021 18:34:44 |
| User entered 'Unknown' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686271

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686272

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered 'Headache - Reactogenicity' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered 'Unkown' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686274

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered 'Unkown' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686276

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered 'unknown (UNKNOWN)' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686277

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686278

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686279

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered 'Unknown' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686280

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686281

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered '0' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686282

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686283

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered '27 Aug 2020' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686284

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:39:24 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:21 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686285

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686286

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686287

**US3292241**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (20)**
**Generated On: 11 Aug 2021 22:21:07**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User entered empty. | System | 21 Apr 2021 18:34:19 |



FDA-CBER-2022-1614-1686288

**US3292241**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures Summary**
**Generated On: 11 Aug 2021 22:21:07**
Were any concomitant procedures performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:10:45 |
| User closed query 'Per source subject had "Punctal Plugs" placed on 06NOV2020 for "Dry Eye." Please update this page to YES and add Con. Procedure.' (Site from CRA). | | 13 Apr 2021 17:10:43 |
| Query 'Per source subject had "Punctal Plugs" placed on 06NOV2020 for "Dry Eye." Please update this page to YES and add Con. Procedure.' answered with 'updated' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:10:10 |
| User entered 'Yes (Y)' reason for change: New Information | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:08:59 |
| User opened query 'Per source subject had "Punctal Plugs" placed on 06NOV2020 for "Dry Eye." Please update this page to YES and add Con. Procedure.' (Site from CRA). | (b) (4), (b) (6) | 11 Feb 2021 20:07:48 |
| User entered 'No (N)' | Dawn Killian (b) (4) (b) (4) | 04 Feb 2021 16:47:08 |

**US3292241**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (1)**
**Generated On: 11 Aug 2021 22:21:07**
Procedure/Surgery date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:10:28 |
| User entered '06 Nov 2020' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:10:44 |



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**US3292241**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (1)**
**Generated On: 11 Aug 2021 22:21:07**
Procedure/Surgery

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:10:28 |
| User entered 'Punctal Plugs' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:10:44 |



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**US3292241**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (1)**
**Generated On: 11 Aug 2021 22:21:07**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:10:28 |
| User entered 'Medical History (MH)' | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:10:44 |



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**US3292241**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (1)**
**Generated On: 11 Aug 2021 22:21:07**
If indication is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:10:28 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Apr 2021 20:10:44 |



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**US3292241**
**Folder: End of Study (1)**
**Form: Dosing Discontinuation**
**Generated On: 11 Aug 2021 22:21:07**
Date of dosing discontinuation (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'This date is equal to date of Dose 1. Subject refused Dose 2 on 24SEP2020 due to AE. (Site from CRA). | | 13 Apr 2021 17:13:43 |
| DataPoint Verified. | | 13 Apr 2021 17:13:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:17:03 |
| Query 'This date is equal to date of Dose 1. Subject refused Dose 2 on 24SEP2020 due to AE.' answered with 'Based on note in source, pt refused second dose on 25sep2020' (Site from CRA). | (b) (4) Antonio Gutierrez (b) (4) | 16 Feb 2021 22:41:24 |
| User entered '25 Sep 2020' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 16 Feb 2021 22:41:13 |
| User opened query 'This date is equal to date of Dose 1. Subject refused Dose 2 on 24SEP2020 due to AE.' (Site from CRA). | (b) (4), (b) (6) | 11 Feb 2021 19:53:42 |
| User entered '20 Aug 2020' | Nathan Cortez (b) (4) | 12 Jan 2021 22:55:59 |



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**US3292241**
**Folder: End of Study (1)**
**Form: Dosing Discontinuation**
**Generated On: 11 Aug 2021 22:21:07**
Primary reason for dosing discontinuation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User closed query 'Per source Subject D/C due to AE.' (Site from CRA). | (b) (4), (b) (6) | 22 Feb 2021 02:39:56 |
| Query 'Per source Subject D/C due to AE.' answered with 'updated' (Site from CRA). | Antonio Gutierrez (b) (4) | 16 Feb 2021 22:42:33 |
| User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 16 Feb 2021 22:41:13 |
| User opened query 'Per source Subject D/C due to AE.' (Site from CRA). | (b) (4), (b) (6) | 11 Feb 2021 20:18:32 |
| User entered 'Other (OTHER)' | Nathan Cortez (b) (4) | 12 Jan 2021 22:55:59 |



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**US3292241**
**Folder: End of Study (1)**
**Form: Dosing Discontinuation**
**Generated On: 11 Aug 2021 22:21:07**
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| User closed query 'Please update with primary AE subject reported as reason for discontinuing IP.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 17:13:56 |
| DataPoint Verified. | | 13 Apr 2021 17:13:55 |
| User closed query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM). | | 31 Mar 2021 16:24:21 |
| Query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' answered with 'updated' (Site from DM). | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:17:16 |
| Signature has been broken. | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:17:01 |
| User entered 'A TEMPERATURE OF 99.8CONSTANT HEADACHES AND FATIGUE, SWOLLEN LYMPHNODES, SWELLING AND PAIN AROUND THE LEFT EYE (AE#1, AE#2, AE#3, AE#4)' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 29 Mar 2021 17:17:01 |
| User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM). | (b) (4), (b) (6) | 02 Mar 2021 19:36:41 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| User entered 'A TEMPERATURE OF 99.8CONSTANT HEADACHES AND FATIGUE, SWOLLEN LYMPHNODES, SWELLING AND PAIN AROUND THE LEFT EYE' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 16 Feb 2021 22:54:10 |
| Query 'Please update with primary AE subject reported as reason for discontinuing IP.' answered with 'updated' (Site from CRA). | Antonio Gutierrez (b) (4) | 16 Feb 2021 22:46:01 |

**US3292241**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 22:21:07**

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

| Audit | User | Time (GMT) |
|---|---|---|
| User entered 'ON 26AUG2020,PATIENT CALLED IN TO REPORT A TEMPERATURE OF 99.8 OVER THE LAST 4-5 DAYS. SHE STATES THIS IS ABNORMAL FOR HER AS SHE TYPICALLY RUNS SUB-NORMAL TEMPERATURES. ADDITIONALLY, SHE REPORTS CONSTANT HEADACHES AND FATIGUE, SWOLLEN LYMPHNODES, SWELLING AND PAIN AROUND THE LEFT EYE. PATIENT REPORTS THAT 26AUG2020 HAS BEEN THE WORST DAY YET IN REGARDS TO SEVERITY OF SYMPTOMS' (non-conformant). | Antonio Gutierrez (b) (4) | 16 Feb 2021 22:45:50 |
| User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System). | System | 16 Feb 2021 22:45:16 |
| User entered 'On 26AUG2020,Patient called in to report a temperature of 99.8 over the last 4-5 days. She states this is abnormal for her as she typically runs sub-normal temperatures. Additionally, she reports constant headaches and fatigue, swollen lymphnodes, swelling and pain around the left eye. Patient reports that today, 26aug2020, has been the worst day yet in regards to severity of symptoms' (non-conformant). | Antonio Gutierrez (b) (4) | 16 Feb 2021 22:45:16 |
| User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System). | System | 16 Feb 2021 22:41:13 |
| User entered empty; reason for change Data Entry Error | Antonio Gutierrez (b) (4) | 16 Feb 2021 22:41:13 |
| User opened query 'Please update with primary AE subject reported as reason for discontinuing IP.' (Site from CRA). | (b) (4), (b) (6) | 11 Feb 2021 20:20:33 |
| User entered 'Patient Decision' | Nathan Cortez (b) (4) | 12 Jan 2021 22:55:59 |

**US3292241**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 11 Aug 2021 22:21:07**
Date of study discontinuation/completion *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:14:59 |
| DataPoint Un-verified. | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:42:30 |
| Signature has been broken. | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:42:30 |
| User entered '31 Dec 2020' reason for change: Data Entry Error | Gerardo Pena (b) (4) (b) (4) | 31 Mar 2021 13:42:30 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Feb 2021 20:17:51 |
| User entered '30 Dec 2020' | Nathan Cortez (b) (4) | 12 Jan 2021 23:01:28 |

**US3292241**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 11 Aug 2021 22:21:07**
Reason for discontinuation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User closed query 'Per CDM: please clarify if the subject received a non-study COVID vaccine PRIOR to withdrawal from the study. If yes, please agree to select protocol deviation. If no, please selection the appropriate reason for discontinuation.' (Site from DM). | | 16 Apr 2021 14:23:48 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:19:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 17:14:56 |
| Query 'Per CDM: please clarify if the subject received a non-study COVID vaccine PRIOR to withdrawal from the study. If yes, please agree to select protocol deviation. If no, please selection the appropriate reason for discontinuation.' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 13 Apr 2021 17:08:55 |
| DataPoint Un-verified. | Dawn Killian (b) (4) (b) (4) | 13 Apr 2021 17:08:50 |
| Signature has been broken. | Dawn Killian (b) (4) (b) (4) | 13 Apr 2021 17:08:50 |
| User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 13 Apr 2021 17:08:50 |
| User opened query 'Per CDM: please clarify if the subject received a non-study COVID vaccine PRIOR to withdrawal from the study. If yes, please agree to select protocol deviation. If no, please selection the appropriate reason for discontinuation.' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 20:07:12 |
| Query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' canceled (Site from DM). | | 09 Apr 2021 20:07:01 |
| User opened query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM). | | 07 Apr 2021 09:07:35 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Feb 2021 20:17:51 |



FDA-CBER-2022-1614-1686299

**US3292241**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 11 Aug 2021 22:21:07**
Reason for discontinuation

| Audit | User | Time (GMT) |
|---|---|---|
| User entered 'Other (OTHER)' | Nathan Cortez (b) (4) | 12 Jan 2021 23:01:28 |



FDA-CBER-2022-1614-1686300

**US3292241**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 11 Aug 2021 22:21:07**
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Feb 2021 20:17:51 |
| User entered 'Patient received EUA vaccination outside of study' | Nathan Cortez (b) (4) | 12 Jan 2021 23:01:28 |



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**US3292241**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 11 Aug 2021 22:21:07**
If reason for discontinuation is Death, main cause of death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Feb 2021 20:17:51 |
| User entered empty. | Nathan Cortez (b) (4) | 12 Jan 2021 23:01:28 |



FDA-CBER-2022-1614-1686302

**US3292241**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 11 Aug 2021 22:21:07**
If main cause of death is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Feb 2021 20:17:51 |
| User entered empty. | Nathan Cortez (b) (4) | 12 Jan 2021 23:01:28 |



FDA-CBER-2022-1614-1686303

**US3292241**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 11 Aug 2021 22:21:07**
Date of death *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Feb 2021 20:17:51 |
| User entered empty. | Nathan Cortez (b) (4) | 12 Jan 2021 23:01:28 |



FDA-CBER-2022-1614-1686304

**US3292241**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 11 Aug 2021 22:21:07**
Was autopsy performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 18:46:52 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Feb 2021 21:17:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Feb 2021 20:17:51 |
| User entered empty. | Nathan Cortez (b) (4) | 12 Jan 2021 23:01:28 |



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