

US3642217 (Prod: University of California San Diego)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:16:22

All time stamps listed in this document are displayed in GMT

US3642217

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 17:54:25

Generated On: 10 Jun 2021 09:16:22

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Participant ID

US3642217

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

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US3642217

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 15 SEP 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | SCRN                                    |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 1948   |
| Age                                       | 72   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 72   |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>  |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |  |
| White                                     | True   |
| Black                                     | False  |
| Asian                                     | False  |
| American Indian or Alaska Native          | False  |
| Native Hawaiian or other Pacific Islander | False  |
| Other                                     | False  |
| If race is Other, specify _____           |  |
| Unknown                                   | False  |
| Not reported                              | False  |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 15 SEP 2020                                  |
| Month and Year of Informed Consent (derived)    | SEP 2020                                     |
| Year of Informed Consent (derived)              | 2020   |
| Protocol Version                                | Amendment 1 <input type="radio"/>            |
|   | Amendment 2 <input type="radio"/>            |
|   | Amendment 3 <input checked="" type="radio"/> |
|   | Amendment 4 <input type="radio"/>            |
|   | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/>         |
|   | No <input type="radio"/>                     |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/>       |
|   | Inclusion/Exclusion <input type="radio"/>    |
|   | Cohort Full <input type="radio"/>            |
|   | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify     |  |
| Was this participant screened previously?       | Yes <input type="radio"/>                    |
|   | No <input checked="" type="radio"/>          |
| If Yes, previous participant number             |  |
| Enrollment Trigger                              | 1  |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Condition   | HYPETENSION  |
| Start date (dd MMM yyyy)                          | UN UNK 1985  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 1985   |
| Start Year (derived)                              | 1985   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Condition   | TYPE 2 DIABETES  |
| Start date (dd MMM yyyy)                          | UN UNK 2016  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2016   |
| Start Year (derived)                              | 2016   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

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

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Form: Medical History (5)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Condition   | POST MENOPAUSAL  |
| Start date (dd MMM yyyy)                          | UN UNK 1985  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 1985   |
| Start Year (derived)                              | 1985   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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



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Form: Medical History (10)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|   |  |
|---|--|
| Condition   | FEMORAL BYPASS SURGERY   |
| Start date (dd MMM yyyy)                          | UN UNK 2015  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2015  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2015   |
| Start Year (derived)                              | 2015   |
| Stop Month and Year (derived)                     | JAN 2015   |
| Stop Year (derived)                               | 2015   |

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Form: Medical History (11)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Condition   | CORONARY ARTERY DISEASE  |
| Start date (dd MMM yyyy)                          | UN UNK 2015  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2015   |
| Start Year (derived)                              | 2015   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|   |  |
|---|--|
| Condition   | CHRONIC KIDNEY DISEASE<br>STAGE 3A                               |
| Start date (dd MMM yyyy)                          |  |
| Start date completely unknown                     | True   |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    |  |
| Start Year (derived)                              |  |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

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

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Form: Medical History (14)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

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

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Form: Medical History (15)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Condition   | ARTERIAL STENOSIS  |
| Start date (dd MMM yyyy)                                | UN UNK 2015  |
| Start date completely unknown                           | False  |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ |  |
| Stop date completely unknown                            | False  |
| Start Month and Year (derived)                          | JAN 2015   |
| Start Year (derived)                                    | 2015   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |



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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Condition   | PULMONARY NODULES  |
| Start date (dd MMM yyyy)                          | UN SEP 2014  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | SEP 2014   |
| Start Year (derived)                              | 2014   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Condition   | PERIPHERAL VASCULAR DISEASE                                      |
| Start date (dd MMM yyyy)                          | UN UNK 2014  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2014   |
| Start Year (derived)                              | 2014   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Condition   | ATHEROSCLEROSIS OF AORTA   |
| Start date (dd MMM yyyy)                          | UN AUG 2016  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | AUG 2016   |
| Start Year (derived)                              | 2016   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

US3642217

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Condition   | COPD   |
| Start date (dd MMM yyyy)                                | UN UNK 2015  |
| Start date completely unknown                           | False  |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ |  |
| Stop date completely unknown                            | False  |
| Start Month and Year (derived)                          | JAN 2015   |
| Start Year (derived)                                    | 2015   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

US3642217

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

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

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Condition   | LEFT BUNDLE BRANCH BLOCK   |
| Start date (dd MMM yyyy)                                | UN UNK 2016  |
| Start date completely unknown                           | False  |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ |  |
| Stop date completely unknown                            | False  |
| Start Month and Year (derived)                          | JAN 2016   |
| Start Year (derived)                                    | 2016   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| Condition   | HEART FAILURE WITH A<br>NORMAL EJECTION FRACTION                 |
| Start date (dd MMM yyyy)                          | UN AUG 2019  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | AUG 2019   |
| Start Year (derived)                              | 2019   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

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



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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

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

US3642217

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

|   |                                      |
|---|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|   | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 15 SEP 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 14:08 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 15 SEP 2020 14:08                    |
| Height ( <i>xxx.x</i> )                   | 155 cm                               |
| Weight ( <i>xxx.x</i> )                   | 67.2 kg                              |
| BMI ( <i>xxx.x</i> )                      | 27.97086 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|   | Axillary <input type="radio"/>       |
|   | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Date of assessment (dd MMM yyyy) 15 SEP 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 1985

Date of last menstruation unknown False

US3642217

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

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

**No Risk Identified** False

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

US3642217

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

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

US3642217

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 15 SEP 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT1                                  |

US3642217

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

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

What was the participant's randomization number? 191017

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒



US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

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

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| Timepoint                           | Pre-Dose <input checked="" type="radio"/><br>Post-Dose <input type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 15 SEP 2020  |
| Time of assessment (00:00-23:59)    | 14:08 (24 HR)  |
| Vital Signs Date and Time (derived) | 15 SEP 2020 14:08  |
| Temperature (xxx.x)                 | 98.2 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 80 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 147 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 77 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| Timepoint                           | Pre-Dose <input type="radio"/><br>Post-Dose <input checked="" type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 15 SEP 2020  |
| Time of assessment (00:00-23:59)    | 16:29 (24 HR)  |
| Vital Signs Date and Time (derived) | 15 SEP 2020 16:29  |
| Temperature (xxx.x)                 | 97.9 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 73 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 128 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 65 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3642217

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

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.*

US3642217

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 15 SEP 2020

What was the treatment time? (00:00-23:59) 15:53 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 15:53

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

What was the frequency of the study treatment dosing? ONCE

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

US3642217

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 SEP 2020

Collection time (00:00-23:59)

15:17 (24 HR)

Collection date and time (derived)

15 SEP 2020 15:17

US3642217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 15 SEP 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 15:24                           | 15 SEP 2020 15:24                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3642217

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 16:27

PC Open Date & Time

15 SEP 2020 16:13

PC Close Date & Time

15 SEP 2020 18:43

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 15 SEP 2020 19:38

PC Close Date & Time 16 SEP 2020 11:59

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:16:22

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 18:46

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 22:43

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 21:14

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**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 <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 97.8 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 19 SEP 2020 21:00 |
| PC Open Date & Time  | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 18:37

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 16:28

PC Open Date & Time

15 SEP 2020 16:13

PC Close Date & Time

15 SEP 2020 18:43

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 SEP 2020 19:38

PC Close Date & Time

16 SEP 2020 11:59

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 18:48

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 22:44

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 21:15

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 21:00

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 18:38

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 15 SEP 2020 16:34 |
| PC Open Date & Time  | 15 SEP 2020 16:13 |
| PC Close Date & Time | 15 SEP 2020 18:43 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐
- Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

- None ☐
- No interference with activity or  
1-2 episodes/24 hours ☐
- Some interference with activity  
or >2 episodes/24 hours ☐
- Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

- None ☐
- No interference with activity ☐
- Some interference with activity  
not requiring medical attention ☐
- Prevents daily activity and  
requires medical attention ☐

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

15 SEP 2020 19:38

PC Close Date & Time

16 SEP 2020 11:59

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 16 SEP 2020 18:49 |
| PC Open Date & Time          | 16 SEP 2020 12:00 |
| PC Close Date & Time         | 17 SEP 2020 11:59 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 17 SEP 2020 22:45 |
| PC Open Date & Time          | 17 SEP 2020 12:00 |
| PC Close Date & Time         | 18 SEP 2020 11:59 |



US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 18 SEP 2020 21:16 |
| PC Open Date & Time          | 18 SEP 2020 12:00 |
| PC Close Date & Time         | 19 SEP 2020 11:59 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 19 SEP 2020 21:01 |
| PC Open Date & Time          | 19 SEP 2020 12:00 |
| PC Close Date & Time         | 20 SEP 2020 11:59 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 20 SEP 2020 18:38 |
| PC Open Date & Time          | 20 SEP 2020 12:00 |
| PC Close Date & Time         | 21 SEP 2020 11:59 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Yes ☐

PC Time stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3642217

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642217

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642217

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642217

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642217

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642217

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 13 OCT 2020 |
|--------------------------|-------------|

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

|            |        |
|------------|--------|
| Folder OID | VISIT2 |
|------------|--------|

US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

|                                     |   |
|-------------------------------------|---|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of assessment (dd MMM yyyy)    | 13 OCT 2020                               |
| Time of assessment (00:00-23:59)    | 13:58 (24 HR)                             |
| Vital Signs Date and Time (derived) | 13 OCT 2020 13:58                         |
| Temperature (xxx.x)                 | 99.1 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 72 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 16 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 135 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 75 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |



US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

|                                     |   |
|-------------------------------------|---|
| Timepoint                           | Pre-Dose <input type="checkbox"/>             |
|                                     | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed?          | Yes <input checked="" type="checkbox"/>       |
|                                     | No <input type="checkbox"/>                   |
| Date of assessment (dd MMM yyyy)    | 13 OCT 2020                                   |
| Time of assessment (00:00-23:59)    | 16:27 (24 HR)                                 |
| Vital Signs Date and Time (derived) | 13 OCT 2020 16:27                             |
| Temperature (xxx.x)                 | 98.1 F  |
| Route of measurement                | Oral <input checked="" type="checkbox"/>      |
|                                     | Axillary <input type="checkbox"/>             |
|                                     | Other <input type="checkbox"/>                |
| If Other, specify                   |   |
| Pulse (xxx)                         | 63 beats/min                                  |
| Pulse units                         | BPM   |
| Respiratory Rate (xxx)              | 17 breaths/min                                |
| Respiratory Rate units              | BREATHS/MIN                                   |
| Systolic Blood Pressure (xxx)       | 127 mmHg                                      |
| Systolic Blood Pressure units       | MMHG  |
| Diastolic Blood Pressure (xxx)      | 70 mmHg                                       |
| Diastolic Blood Pressure units      | MMHG  |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3642217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 OCT 2020

What was the treatment time? (00:00-23:59) 15:56 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 15:56

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

What was the frequency of the study treatment dosing? ONCE

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

US3642217

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

15:42 (24 HR)

Collection date and time (derived)

13 OCT 2020 15:42

US3642217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 13 OCT 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 15:45                           | 13 OCT 2020 15:45                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 16:26

PC Open Date & Time

13 OCT 2020 16:16

PC Close Date & Time

13 OCT 2020 18:46

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 13 OCT 2020 23:02 |
| PC Open Date & Time  | 13 OCT 2020 19:41 |
| PC Close Date & Time | 14 OCT 2020 11:59 |



US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 18:42

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 19:48

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 21:43

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 21:46

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 19:04

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

19 OCT 2020 19:36

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59



US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 16:28

PC Open Date & Time

13 OCT 2020 16:16

PC Close Date & Time

13 OCT 2020 18:46

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 23:02

PC Open Date & Time

13 OCT 2020 19:41

PC Close Date & Time

14 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 18:49

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 19:49

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 21:44

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 21:47

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 19:05

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 19:37

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59



US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 13 OCT 2020 16:29 |
| PC Open Date & Time  | 13 OCT 2020 16:16 |
| PC Close Date & Time | 13 OCT 2020 18:46 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 13 OCT 2020 23:03 |
| PC Open Date & Time  | 13 OCT 2020 19:41 |
| PC Close Date & Time | 14 OCT 2020 11:59 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 14 OCT 2020 18:49 |
| PC Open Date & Time          | 14 OCT 2020 12:00 |
| PC Close Date & Time         | 15 OCT 2020 11:59 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 15 OCT 2020 19:50 |
| PC Open Date & Time          | 15 OCT 2020 12:00 |
| PC Close Date & Time         | 16 OCT 2020 11:59 |



US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 16 OCT 2020 21:44 |
| PC Open Date & Time          | 16 OCT 2020 12:00 |
| PC Close Date & Time         | 17 OCT 2020 11:59 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 17 OCT 2020 21:48 |
| PC Open Date & Time          | 17 OCT 2020 12:00 |
| PC Close Date & Time         | 18 OCT 2020 11:59 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 18 OCT 2020 19:05 |
| PC Open Date & Time          | 18 OCT 2020 12:00 |
| PC Close Date & Time         | 19 OCT 2020 11:59 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 19 OCT 2020 19:37 |
| PC Open Date & Time          | 19 OCT 2020 12:00 |
| PC Close Date & Time         | 20 OCT 2020 11:59 |



US3642217

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:16:22

|   |                              |
|---|------------------------------|
| <b>TIMEPOINT</b>  | DAY 8                        |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input type="checkbox"/>  |
|   | Yes <input type="checkbox"/> |
| PC Time stamp   |                              |
| PC Open Date & Time   | 20 OCT 2020 12:00            |
| PC Close Date & Time  | 21 OCT 2020 11:59            |

US3642217

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:16:22

|   |                              |
|---|------------------------------|
| <b>TIMEPOINT</b>  | DAY 9                        |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input type="checkbox"/>  |
|   | Yes <input type="checkbox"/> |
| PC Time stamp   |                              |
| PC Open Date & Time   | 21 OCT 2020 12:00            |
| PC Close Date & Time  | 22 OCT 2020 11:59            |

US3642217

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642217

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642217

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642217

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642217

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642217

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3642217

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 10 NOV 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT3                                  |

US3642217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

|   |                                       |
|---|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|   | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 10 NOV 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 14:19 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 10 NOV 2020 14:19                     |
| Temperature ( <i>xxx.x</i> )              | 98.3 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|   | Axillary <input type="radio"/>        |
|   | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 72 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 14 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 127 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 66 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3642217

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

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.*

US3642217

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 NOV 2020

Collection time (00:00-23:59)

14:43 (24 HR)

Collection date and time (derived)

10 NOV 2020 14:43

US3642217

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 17:54:59

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 18:11:43

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 68   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 23 NOV 2020 19:12:08   |
| Patient Cloud Open Date & Time  | 19 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 23 NOV 2020 23:59  |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 75  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2020 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 82  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 89   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 10 DEC 2020 10:34:43   |
| Patient Cloud Open Date & Time  | 10 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 14 DEC 2020 23:59  |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 96   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 17 DEC 2020 12:04:36   |
| Patient Cloud Open Date & Time  | 17 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 21 DEC 2020 23:59  |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 103  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission   | 24 DEC 2020 14:23:54   |
| Patient Cloud Open Date & Time  | 24 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 28 DEC 2020 23:59  |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

Date and time of submission

31 DEC 2020 18:15:40

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 17:55:26

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59



US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 124  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission   | 14 JAN 2021 10:14:04   |
| Patient Cloud Open Date & Time  | 14 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 18 JAN 2021 23:59  |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 09:08:47

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 04:30:00

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 145  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission   | 04 FEB 2021 18:19:54   |
| Patient Cloud Open Date & Time  | 04 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 08 FEB 2021 23:59  |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 13:43:26

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 159  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission   | 18 FEB 2021 12:42:53   |
| Patient Cloud Open Date & Time  | 18 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 22 FEB 2021 23:59  |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 09:29:12

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 23:58:27

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59



US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 13:33:17

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 10:34:50

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 23:18:51

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 08:26:50

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 10:37:22

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 14:43:32

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 222  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 APR 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

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29 APR 2021 13:20:46

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 236  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 243  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 250  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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20 MAY 2021 00:01

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24 MAY 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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



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**Form: Safety Follow Up Diary**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 264  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 271  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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10 JUN 2021 00:01

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14 JUN 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

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17 JUN 2021 00:01

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21 JUN 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 285  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |



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**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 292  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 299   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 320   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 334  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 341  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 348  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 16 SEP 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 SEP 2021 23:59 |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 390   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 397

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 14 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 18 OCT 2021 23:59 |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 404  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 411   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 418   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 425   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 NOV 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 NOV 2021 23:59 |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 446   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 460   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 16 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 DEC 2021 23:59 |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 467  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 481   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 10 MAR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 MAR 2022 23:59 |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3642217**

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**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 600  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 614  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

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26 MAY 2022 00:01

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30 MAY 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 628   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

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

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**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

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13 JUN 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 642   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

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20 JUN 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

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27 JUN 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 30 JUN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 04 JUL 2022 23:59 |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 663   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 670   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 691  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 698

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 AUG 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 AUG 2022 23:59 |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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



**US3642217**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

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22 AUG 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 712   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 25 AUG 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 AUG 2022 23:59 |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 719   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

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01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 726   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

Date and time of submission

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08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 740   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 SEP 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 747  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 06 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 10 OCT 2022 23:59 |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 13 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 OCT 2022 23:59 |

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

| TIMEPOINT   | DAY 768   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 OCT 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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



**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 10 NOV 2022 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 NOV 2022 23:59 |
|---|-------------------|

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US3642217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 NOV 2022 23:59

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US3642217

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:16:22

| 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            |
|---|--|--------------------------------------|
| <a href="#">Yes</a>   | <a href="#">No</a>   | <a href="#">04 MAR 2021 23:58:55</a> |

US3642217

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642217

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642217

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642217

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3642217

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642217

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642217

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 02:20:57

Generated On: 10 Jun 2021 09:16:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642217

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 02:20:57

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642217

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Apr 2021 18:05:12

Generated On: 10 Jun 2021 09:16:22

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 12 APR 2021 |
|--------------------------|-------------|

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

|            |        |
|------------|--------|
| Folder OID | VISIT4 |
|------------|--------|

US3642217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Apr 2021 18:05:12

Generated On: 10 Jun 2021 09:16:22

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3642217

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Apr 2021 18:05:12

Generated On: 10 Jun 2021 09:16:22

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.*

US3642217

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Apr 2021 18:05:12

Generated On: 10 Jun 2021 09:16:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 APR 2021

Collection time (00:00-23:59)

14:19 (24 HR)

Collection date and time (derived)

12 APR 2021 14:19



US3642217

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 18:05:12

Generated On: 10 Jun 2021 09:16:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3642217**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3642217**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3642217

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:16:22

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

**US3642217**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:16:22**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3642217

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 17:54:29

Generated On: 10 Jun 2021 09:16:22

|                           |                                      |
|---------------------------|--------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
|                           | No <input type="radio"/>             |

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 21 JAN 2021 |
|--------------------------|-------------|

|   |   |
|---|---|
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |

|            |               |
|------------|---------------|
| Folder OID | UNBLND_DECIDE |
|------------|---------------|

US3642217

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 13 Mar 2021 02:20:57

Generated On: 10 Jun 2021 09:16:22

Date of updated informed consent (dd MMM yyyy) 21 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 21 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3642217

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Mar 2021 01:50:26

Generated On: 10 Jun 2021 09:16:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00-23:59)

16:02 (24 HR)

Collection date and time (derived)

21 JAN 2021 16:02



US3642217

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 06 Mar 2021 01:50:26

Generated On: 10 Jun 2021 09:16:22

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 21 JAN 2021                          |
| Collection time (00:00 - 23:59)    | 16:04                                |
| Collection Date and Time (derived) | 21 JAN 2021 16:04                    |

US3642217

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 17:54:26

Generated On: 10 Jun 2021 09:16:22

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3642217

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 18:05:11

Generated On: 10 Jun 2021 09:16:22

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | PIRIFORMIS SYNDROME  |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 06 OCT 2020  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         |  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | False  |
| Hospital Admission Date (dd MMM yyyy)                          |  |
| Hospital Discharge Date (dd MMM yyyy)                          |  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |
| Number of Days in ICU  |  |

US3642217

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 18:05:11

Generated On: 10 Jun 2021 09:16:22

|  |   |
|--|---|
| Persistent or significant disability or incapacity                           | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input checked="" type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input checked="" type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |

US3642217

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 18:05:11

Generated On: 10 Jun 2021 09:16:22

---

ATIENT REPORTS RIGHT HIP  
PAIN SINCE MAY 2020 AND  
WAS DIAGNOSED WITH  
PIRIFORMIS SYNDROME BY  
PCP ON 10/6/20. AE MEDICALLY  
ATTENDED RESULTING IN NEW  
MEDICATION.  
UPDATE: PATIENT FOLLOWED  
UP WITH PCP WHO  
RECOMMENDED  
ALTERNATING TYLENOL AND  
IBUPROFEN FOR HIP PAIN  
RELATED TO PIRIFORMIS  
SYNDROME. PATIENT  
REPORTS SOME IMPROVEMENT  
IN PAIN.

---

|  |   |
|--|---|
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only)       |   |

---

---

US3642217

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 18:05:11

Generated On: 10 Jun 2021 09:16:22

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | BILATERAL LOWER LEGS<br>TINGLING   |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 08 DEC 2020  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         |  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | False  |
| Hospital Admission Date (dd MMM yyyy)                          |  |
| Hospital Discharge Date (dd MMM yyyy)                          |  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |

US3642217

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 18:05:11

Generated On: 10 Jun 2021 09:16:22

|  |   |
|--|---|
| Number of Days in ICU  |   |
| Persistent or significant disability or incapacity                           | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/>                |
|  | Related <input type="radio"/>                               |
|  | Not Applicable <input type="radio"/>                        |
| Relationship to Study Procedure  | Not Related <input type="radio"/>                           |
|  | Related <input type="radio"/>                               |
|  | Not Applicable <input checked="" type="radio"/>             |
| Action taken with investigational product                                    | None <input type="radio"/>                                  |
|  | Dose Delayed <input type="radio"/>                          |
|  | Investigational Product Withdrawn <input type="radio"/>     |
|  | Not Applicable <input checked="" type="radio"/>             |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/>                                 |
|  | Not Recovered/Not Resolved <input checked="" type="radio"/> |
|  | Recovered/Resolved <input type="radio"/>                    |
|  | Recovered/Resolved with Sequelae <input type="radio"/>      |
|  | Recovering/Resolving <input type="radio"/>                  |
|  | Unknown <input type="radio"/>                               |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |

US3642217

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 18:05:11

Generated On: 10 Jun 2021 09:16:22

---

SUBJECT REPORTED  
BILATERAL LOWER LEG  
TINGLING. SHE HAD HER MRI  
THROUGH KAISER AND IT  
SHOWED "BULGING DISKS L3-5".  
THEY RECOMMENDED SOME  
SORT OF LUMBAR INJECTION  
FOR HER BUT SHE IS UNABLE  
TO GET IT AT THIS TIME  
BECAUSE THOSE PROCEDURES  
ARE ON HOLD AT KAISER DUE  
TO COVID-19.

---

|  |   |
|--|---|
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only)       |   |

---

---



US3642217

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Apr 2021 18:05:11

Generated On: 10 Jun 2021 09:16:22

|  |  |
|--|--|
| AEID   | USA-US109-2021-MRNA-1273-P30<br>1000006  |
| Adverse event  | ATHEROSCLEROSIS OF<br>BILATERAL LEGS   |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 1 FEB 2021   |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         | 16 FEB 2021  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | True   |
| Hospital Admission Date (dd MMM yyyy)                          | 16 FEB 2021  |
| Hospital Discharge Date (dd MMM yyyy)                          | 17 FEB 2021  |
| Admitted to ICU?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>  |
| PRODUCTION RELEASE (v12.003<br>EAB) (1725)                     | 360 of 3077  |

US3642217

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Apr 2021 18:05:11

Generated On: 10 Jun 2021 09:16:22

|  |   |
|--|---|
| Number of Days in ICU  | 1   |
| Persistent or significant disability or incapacity                                 | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product  | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>  |
| Other action taken (check all that apply)  |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | True  |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ |   |
| Narrative  |   |

US3642217

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Apr 2021 18:05:11

Generated On: 10 Jun 2021 09:16:22

---

SUBJECT REPORTS THAT SHE  
WAS DIAGNOSED WITH  
PERIPHERAL AORTIC/ILLIAC  
STENOSIS CONTRIBUTING TO  
THE ONGOING BURNING AND  
TINGLING SHE HAS BEEN  
EXPERIENCING IN HER LEGS.  
SHE REQUIRED SURGERY TO  
HAVE STENTS PLACED ON  
16FEB2021. SHE REQUIRED  
OVERNIGHT STAY IN ICU FOR 1  
NIGHT AND WAS DISCHARGED  
THE FOLLOWING DAY. SHE IS  
RECOVERING AT HOME AND  
REMAINS ON STUDY.

---

|  |   |
|--|---|
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only)       | 1 |

---

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 18:05:11

Generated On: 10 Jun 2021 09:16:22

AEID

Adverse event

LEFT INNER THIGH SURGICAL  
SITE INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

1 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 18:05:11

Generated On: 10 Jun 2021 09:16:22

|  |   |
|--|---|
| Number of Days in ICU  |   |
| Persistent or significant disability or incapacity                           | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>  |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | True  |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 18:05:11

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SUBJECT HAD SURGERY (ANGIOPLASTY AND STENT INSERTION) ON 16FEB2021 FOR HER HISTORY OF PAD WHERE THEY PUT IN 3 STENTS. ON 01MAR2021 SHE HAD A FOLLOW UP WITH HER SURGEON. THE SURGEON NOTICED THAT THE SURGICAL SITE (HER LEFT INNER THIGH) LOOKED LIKE IT WAS INFECTED. ON 01MAR2021 SHE WAS THEN PRESCRIBED DOXYCYCLINE 100MG PO BID STARTED ON 01MAR2021 X 14 DAYS FOR THE SURGICAL SITE INFECTION. THE MEDICATION WAS STOPPED ON 15MAR2021. SUBJECT WAS CONTACTED ON 17MAR2021 FOR FOLLOW UP – SHE STATES THAT THE INFECTED SURGICAL SITE IS STILL HEALING BUT HAS GREATLY IMPROVED. FOLLOW UP ON 19MAR2021 – PER SUBJECT SURGICAL SITE INFECTION HAS RESOLVED WITH NO ISSUES.

---

|  |   |
|--|---|
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only)       |   |

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Folder: Adverse Events

Form: Adverse Events (5)

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|  |  |
|--|--|
| AEID   | USA-US109-2021-MRNA-1273-P30<br>1000006  |
| Adverse event  | INTERMITTENT<br>CLAUDICATION   |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 01 FEB 2021  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         | 16 FEB 2021  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | True   |
| Hospital Admission Date (dd MMM yyyy)                          | 16 FEB 2020  |
| Hospital Discharge Date (dd MMM yyyy)                          | 17 FEB 2020  |
| Admitted to ICU?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>  |
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Form: Adverse Events (5)

Data signed: (b) (4) 19 Apr 2021 18:05:11

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|  |   |
|--|---|
| Number of Days in ICU  | 1   |
| Persistent or significant disability or incapacity                                 | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product  | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>  |
| Other action taken (check all that apply)  |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | True  |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ |   |
| Narrative  |   |



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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Apr 2021 18:05:11

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SUBJECT REPORTS THAT SHE  
WAS DIAGNOSED WITH  
PERIPHERAL AORTIC/ILLIAC  
STENOSIS CONTRIBUTING TO  
THE ONGOING BURNING AND  
TINGLING SHE HAS BEEN  
EXPERIENCING IN HER LEGS.  
SHE REQUIRED SURGERY TO  
HAVE STENTS PLACED ON  
16FEB2021. SHE REQUIRED  
OVERNIGHT STAY IN ICU FOR 1  
NIGHT AND WAS DISCHARGED  
THE FOLLOWING DAY. SHE IS  
RECOVERING AT HOME AND  
REMAINS ON STUDY.

---

|  |   |
|--|---|
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only)       | 1 |

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US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 17:54:29

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

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If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 60

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | UN UNK 2010              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 06 NOV 2020              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | 1                        |                                     |
| Interval Dosage Unit Number (derived)              | 1                        |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication ESTRADIOL 0.1% GEL

Prophylaxis Yes ☐  
No ☒

Indication VAGINAL DRYNESS

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify TWICE PER WEEK

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input checked="" type="checkbox"/> |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | UN MAY 2020              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input type="checkbox"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication CETIRIZINE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGY

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2019              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 75

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | UN UNK 2015              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 20 JAN 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | 1                        |                                     |
| Interval Dosage Unit Number (derived)              | 1                        |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication BUPROPION

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 300

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2018              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication AMLODOPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2018              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2019              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2016              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 2                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication HEART PROPHYLAXIS

Dose per administration 81

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2015              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication MAGNESIUM

Prophylaxis Yes ☐  
No ☒

Indication SUPPLEMENT

Dose per administration 250

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2019              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication MULTI VITAMIN

Prophylaxis Yes ☐  
No ☒

Indication SUPPLEMENT

Dose per administration 200

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☒  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2019              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication IRON D3

Prophylaxis Yes ☐  
No ☒

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2019              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication CINNAMON

Prophylaxis Yes ☐  
No ☒

Indication SUPPLEMENT

Dose per administration 1000

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2018              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR FLU

Dose per administration 0.5

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input checked="" type="radio"/> |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input type="radio"/>            |
|  | Intravenous              | <input type="radio"/>            |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 30 OCT 2020                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 30 OCT 2020                      |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HIP PAIN (RIGHT)

Dose per administration 1000

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 19 SEP 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 19 SEP 2020 |                          |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PIRIFORMIS SYNDROME

Dose per administration 1000

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 06 OCT 2020                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   |                          | _____                            |
| Interval Dosage Unit Number (derived)              |                          | _____                            |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication PIRIFORMIS SYNDROME

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 06 OCT 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 08 OCT 2020 |                          |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   |                          | 1                                   |
| Interval Dosage Unit Number (derived)              |                          | 1                                   |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication PIRIFORMIS SYNDROME

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 09 OCT 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 11 OCT 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   |                          | 1                                   |
| Interval Dosage Unit Number (derived)              |                          | 1                                   |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 06 NOV 2020                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   |                          | 1                                |
| Interval Dosage Unit Number (derived)              |                          | 1                                |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication PLAVIX

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 75

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Transdermal              | <input type="checkbox"/>         |
|  | Intraocular              | <input type="checkbox"/>         |
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 17 FEB 2021              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL LEG TINGLING

Dose per administration 300

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☒  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|  |                                      |                                     |
|--|--------------------------------------|-------------------------------------|
|  | Intramuscular                        | <input type="checkbox"/>            |
|  | Respiratory (Inhalation)             | <input type="checkbox"/>            |
|  | Intralesional                        | <input type="checkbox"/>            |
|  | Intraperitoneal                      | <input type="checkbox"/>            |
|  | Nasal                                | <input type="checkbox"/>            |
|  | Vaginal                              | <input type="checkbox"/>            |
|  | Rectal                               | <input type="checkbox"/>            |
|  | Intravenous                          | <input type="checkbox"/>            |
|  | Intravenous Bolus                    | <input type="checkbox"/>            |
|  | Intravenous Drip                     | <input type="checkbox"/>            |
|  | Other                                | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                                      |                                     |
| Start date (dd MMM yyyy)                           |                                      | 17 FEB 2021                         |
| Start date completely unknown                      |                                      | False                               |
| Ongoing?   | Yes <input type="checkbox"/>         | No <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) 12 APR 2021 |                                      |                                     |
| Was this medication taken for solicited event?     | Yes <input type="checkbox"/>         | No <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   |                                      | 3                                   |
| Interval Dosage Unit Number (derived)              |                                      | 1                                   |
| Interval Dosage Definition (derived)               | 802 <input type="checkbox"/>         |                                     |
|  | 803 <input type="checkbox"/>         |                                     |
|  | 804 <input checked="" type="radio"/> |                                     |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 650

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

EVERY 4 HOURS

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 17 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☒  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Transdermal              | <input type="checkbox"/>         |
|  | Intraocular              | <input type="checkbox"/>         |
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 4                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication HEPARIN

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 5,000

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 17 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 17 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | 2                        |                                     |
| Interval Dosage Unit Number (derived)              | 1                        |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication PLAVIX (LOADING DOSE)

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 300

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 16 FEB 2021                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication CEFAZOLIN (PRE-OP)

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 2

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☒  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication CEFAZOLIN (POST-OP)

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 2

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☒  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

EVERY 8 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 17 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication FENTANYL (PF) BOLUS

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 100

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication LIDOCAINE

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 50

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication PROPOFOL

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 150

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication ROCURONIUM

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 400

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication EPHEDRINE

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 2.5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

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Name of Medication DEXMEDETOMIDINE

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 29.01

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication PHENYLEPHRINE 40 MG IN  
SODIUM CHLORIDE 0.9% 250 ML  
IV SOLN

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 3341.67

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

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|  |  |                                     |
|--|--|-------------------------------------|
|  | Topical                                | <input type="checkbox"/>            |
|  | Subcutaneous                           | <input type="checkbox"/>            |
|  | Transdermal                            | <input type="checkbox"/>            |
|  | Intraocular                            | <input type="checkbox"/>            |
|  | Intramuscular                          | <input type="checkbox"/>            |
|  | Respiratory (Inhalation)               | <input type="checkbox"/>            |
|  | Intralesional                          | <input type="checkbox"/>            |
|  | Intraperitoneal                        | <input type="checkbox"/>            |
|  | Nasal                                  | <input type="checkbox"/>            |
|  | Vaginal                                | <input type="checkbox"/>            |
|  | Rectal                                 | <input type="checkbox"/>            |
|  | Intravenous                            | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus                      | <input type="checkbox"/>            |
|  | Intravenous Drip                       | <input type="checkbox"/>            |
|  | Other                                  | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |  |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021                            |                                     |
| Start date completely unknown                      | False                                  |                                     |
| Ongoing?   | Yes <input type="checkbox"/>           |                                     |
|  | No <input checked="" type="checkbox"/> |                                     |
| If not Ongoing, End date (dd MMM yyyy)             |  | 16 FEB 2021                         |
| Was this medication taken for solicited event?     | Yes <input type="checkbox"/>           |                                     |
|  | No <input checked="" type="checkbox"/> |                                     |
| Separate Dosage Number (derived) _____             |  |                                     |
| Interval Dosage Unit Number (derived) _____        |  |                                     |
| Interval Dosage Definition (derived)               | 802                                    | <input type="checkbox"/>            |
|  | 803                                    | <input type="checkbox"/>            |
|  | 804                                    | <input type="checkbox"/>            |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 500

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication HEPARIN

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 7000

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 16 FEB 2021                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 4

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 507.5

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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Name of Medication SUGAMMADEX

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF  
BILATERAL LEGS WITH  
INTERMITTENT  
CLAUDICATION

Dose per administration 130

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 16 FEB 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐  
No ☒

Indication LEFT INNER THIGH SURGICAL  
SITE INFECTION

Dose per administration 100

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 23 Apr 2021 20:51:21

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify   |                          |                                     |
| Start date (dd MMM yyyy)                       | 1 MAR 2021               |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 15 MAR 2021              |                                     |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 2                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 20 JAN 2021              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL LOWER LEG  
TINGLING

Dose per administration 100

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☒  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="checkbox"/>         |
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 12 APR 2021                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   |                          | 3                                |
| Interval Dosage Unit Number (derived)              |                          | 1                                |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication VITAMIN B12

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR VITAMIN  
B12 DEFICIENCY

Dose per administration 1000

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

TWICE A WEEK

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="checkbox"/>         |
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 01 MAR 2021                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   |                          | _____                            |
| Interval Dosage Unit Number (derived)              |                          | _____                            |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication PIRIFORMIS SYNDROME

Dose per administration 600

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 21 OCT 2020              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | _____                    |                                  |
| Interval Dosage Unit Number (derived)              | _____                    |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Mar 2021 02:20:57

Generated On: 10 Jun 2021 09:16:22

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Apr 2021 20:51:21

Generated On: 10 Jun 2021 09:16:22

| Procedure/Surgery date (dd MMM<br>yyyy) | Procedure/Surgery                   | Indication      | If indication is Other, specify |
|---|-------------------------------------|-----------------|---------------------------------|
| 31 DEC 2020                             | MRI OF LOWER LEG                    | Adverse Event   |                                 |
| 16 FEB 2021                             | ANGIOPLASTY WITH STENT<br>INSERTION | Medical History |                                 |
| 01 JAN 2021                             | MRI OF BACK                         | Medical History |                                 |

US3642217

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:16:22

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3642217

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:16:22

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐



US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 19 Apr 2021 18:05:12

Generated On: 10 Jun 2021 09:16:22

|  |  |
|--|--|
| SAEID  | USA-US109-2021-MRNA-1273-P301000006                              |
| Serious  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                      | STEPHEN  |
| Investigator's Last Name                                       | SPECTOR  |
| Site Address: Street   |  |
| Site Address: City   |  |
| Site Address: State  |  |
| Site Address: Postal Code                                      |  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 6  |

US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Apr 2021 18:05:12

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| SAEID   | USA-US109-2021-MRNA-1273-P301000006                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | STEPHEN  |
| Investigator's Last Name  | SPECTOR  |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   |  |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 6  |
| Date of submission (Pre-filled from custom function)  | 22/FEB/2021 11:57  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Apr 2021 18:05:12

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| SAEID   | USA-US109-2021-MRNA-1273-P301000006                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | STEPHEN  |
| Investigator's Last Name  | SPECTOR  |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   |  |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 6  |
| Date of submission (Pre-filled from custom function)  | 22/FEB/2021 14:36  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Apr 2021 18:05:12

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| SAEID   | USA-US109-2021-MRNA-1273-P301000006                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | STEPHEN  |
| Investigator's Last Name  | SPECTOR  |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   |  |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 6  |
| Date of submission (Pre-filled from custom function)  | 22/FEB/2021 15:19  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Apr 2021 18:05:12

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| SAEID   | USA-US109-2021-MRNA-1273-P301000006                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | STEPHEN  |
| Investigator's Last Name  | SPECTOR  |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   |  |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 6  |
| Date of submission (Pre-filled from custom function)  | 22/MAR/2021 13:49  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Apr 2021 18:05:12

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| SAEID   | USA-US109-2021-MRNA-1273-P301000006                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | STEPHEN  |
| Investigator's Last Name  | SPECTOR  |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   |  |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 6  |
| Date of submission (Pre-filled from custom function)  | 08/APR/2021 12:09  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Apr 2021 18:05:12

Generated On: 10 Jun 2021 09:16:22

|   |  |
|---|--|
| SAEID   | USA-US109-2021-MRNA-1273-P301000006                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | STEPHEN  |
| Investigator's Last Name  | SPECTOR  |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   |  |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 6  |
| Date of submission (Pre-filled from custom function)  | 14/APR/2021 09:27  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

Audit

US3642217 (Prod: University of California San Diego)



**US3642217**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:16:22**

[Participant ID](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)          | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 08 Dec 2020 19:18:43 |
| User entered 'US3642217'  | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 15 Sep 2020 22:09:24 |

US3642217

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:16:22

[Was this visit performed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:27 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 17:59:07 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:29 |

US3642217

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:16:22

Visit date (dd MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                                  | 02 May 2021 07:09:27 |
| Data hard locked.          |                                  | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)          | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 08 Dec 2020 17:59:07 |
| User entered '15 SEP 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 15 Sep 2020 22:09:25 |

US3642217

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:16:22

Was visit performed at the participant's home or at the clinic?

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.            |                                   | 02 May 2021 07:09:27 |
| Data hard locked.              |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 17:59:07 |
| User entered 'Clinic (Clinic)' | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:29 |

US3642217

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:16:22

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:27 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered 'SCRN' | System           | 15 Sep 2020 22:40:29 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

Date of Birth (MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                                  | 02 May 2021 07:09:31 |
| Data hard locked.          |                                  | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)          | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 08 Dec 2020 18:00:39 |
| User entered (b) (6) 1948' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 15 Sep 2020 22:09:26 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

[Age](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:31 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:39 |
| User entered '72'         | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:56 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                  | 02 May 2021 07:09:31 |
| Data hard locked.    |                  | 28 Apr 2021 19:15:41 |
| User entered 'YEARS' | System           | 15 Sep 2020 22:40:56 |



US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

[Age \(Derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:31 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '72'   | System           | 15 Sep 2020 22:41:10 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

Sex

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:31 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:39 |
| User entered 'Female (F)' | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:56 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

[Ethnicity](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:31 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:39 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:56 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

White

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:31 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:39 |
| User entered 'I'          | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:56 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

[Black](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:31 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:39 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:56 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

[Asian](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:31 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:39 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:56 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

[American Indian or Alaska Native](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:31 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:39 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:56 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:31 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:39 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:56 |



US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

[Other](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:31 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:39 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:56 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

If race is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:31 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:39 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:56 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

Unknown

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:31 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:39 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:56 |

US3642217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:16:22

Not reported

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:31 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:39 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:40:56 |

US3642217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:16:22

Date of Informed Consent (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                                   | 02 May 2021 07:09:35 |
| Data hard locked.          |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:53 |
| User entered '15 Sep 2020' | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:41:10 |

US3642217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:16:22

[Month and Year of Informed Consent \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:35 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Sep 2020' | System           | 15 Sep 2020 22:41:10 |

US3642217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:16:22

[Year of Informed Consent \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:35 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2020' | System           | 15 Sep 2020 22:41:10 |

US3642217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:16:22

[Protocol Version](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.            |                                   | 02 May 2021 07:09:35 |
| Data hard locked.              |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:53 |
| User entered 'Amendment 3 (3)' | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:41:10 |



US3642217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:16:22

[Was participant enrolled in the study?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:35 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:53 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:41:10 |

US3642217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:16:22

If No, indicate reason for screen fail

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:35 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:53 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:41:10 |

US3642217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:16:22

If reason for screen fail is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:35 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:53 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:41:10 |

US3642217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:16:22

[Was this participant screened previously?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:35 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:00:53 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:41:10 |

US3642217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:16:22

[If Yes, previous participant number](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                  | 02 May 2021 07:09:35 |
| Data hard locked.         |                                  | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)          | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 08 Dec 2020 18:00:53 |
| User entered empty.       | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 15 Sep 2020 22:09:25 |

US3642217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:16:22

[Enrollment Trigger](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:35 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '1'    | System           | 15 Sep 2020 22:41:16 |

US3642217

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:16:22

[Did the participant meet all eligibility criteria?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:40 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:02:14 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:41:16 |

US3642217

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:16:22

[Were any significant conditions reported?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:44 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:02:31 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:22:53 |



US3642217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard unlocked.   | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.   |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.   |                                   | 02 May 2021 07:09:50 |
| Data hard locked.   |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.   |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.   | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 02 Feb 2021 00:24:05 |
| User closed query 'Please check and confirm spelling' (Site from CRA).  | (b) (4), (b) (6)                  | 02 Feb 2021 00:24:03 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)   | 22 Jan 2021 21:20:06 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4)   | 22 Jan 2021 21:20:06 |
| Data point term sent to Coder   | System                            | 22 Jan 2021 21:19:11 |
| Query 'Please check and confirm spelling' answered by data change (Site from CRA).  | System                            | 22 Jan 2021 21:18:59 |
| Coding entries removed.   | Megan Loughran (b) (4)<br>(b) (4) | 22 Jan 2021 21:18:59 |
| User entered 'HYPERLIPIdemia' reason for change: Per Query Resolution   | Megan Loughran (b) (4)<br>(b) (4) | 22 Jan 2021 21:18:59 |
| User opened query 'Please check and confirm spelling' (Site from CRA).  | (b) (4), (b) (6)                  | 21 Jan 2021 22:45:27 |
| User closed query 'Please check and confirm spelling' (Site from CRA).  | (b) (4), (b) (6)                  | 21 Jan 2021 22:45:27 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)   | 15 Dec 2020 00:53:45 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3642217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:16:22

Condition

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)   | 15 Dec 2020 00:53:45 |
| Data point term sent to Coder   | (b) (4) System         | 14 Dec 2020 19:06:30 |
| Query 'Please check and confirm spelling. ' answered with 'revised' (Site from CRA).  | Megan Loughran (b) (4) | 14 Dec 2020 19:05:44 |
| Coding entries removed.   | (b) (4)                |                      |
|   | Megan Loughran (b) (4) | 14 Dec 2020 19:05:41 |
|   | (b) (4)                |                      |
| User entered 'HYPERLIPIDERIA' reason for change: Per Query Resolution   | Megan Loughran (b) (4) | 14 Dec 2020 19:05:41 |
|   | (b) (4)                |                      |
| User opened query 'Please check and confirm spelling. ' (Site from CRA).  | (b) (4), (b) (6)       | 08 Dec 2020 18:31:03 |
| DataPoint Un-verified.  |                        |                      |
|   | (b) (4), (b) (6)       | 08 Dec 2020 18:30:42 |
|   |                        |                      |
| DataPoint Verified.   | (b) (4), (b) (6)       | 08 Dec 2020 18:04:52 |
|   |                        |                      |
| User coded data point as SOC: Metabolism and nutrition disorders, HLT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0. | Coder Import (b) (4)   | 17 Sep 2020 21:02:39 |
|   | (b) (4)                |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)   | 17 Sep 2020 21:02:39 |
|   | (b) (4)                |                      |
| Data point term sent to Coder   | System                 | 17 Sep 2020 16:23:56 |
| User entered 'hyperlipidermia'  | Son Do (b) (4)         | 17 Sep 2020 16:23:10 |

US3642217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.          |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                             | 02 May 2021 07:09:50 |
| Data hard locked.          |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.        |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.          |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:52 |
| User entered 'UN UNK 2010' | Son Do (b) (4)              | 17 Sep 2020 16:23:10 |

US3642217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:52 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:23:10 |

US3642217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:52 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:23:10 |

US3642217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:52 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:23:10 |

US3642217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:52 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:23:10 |

US3642217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 2010' | System           | 17 Sep 2020 16:23:10 |



US3642217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2010' | System           | 17 Sep 2020 16:23:10 |

US3642217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 17 Sep 2020 16:23:10 |

US3642217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 17 Sep 2020 16:23:10 |

US3642217

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                | 03 May 2021 19:16:41 |
| Data hard locked.  |                                 | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                 | 02 May 2021 07:09:50 |
| Data hard locked.  |                                 | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                 | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                 | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)         | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 08 Dec 2020 18:04:55 |
| 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)<br>(b) (4) | 17 Sep 2020 16:24:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:24:38 |
| Data point term sent to Coder  | System                          | 17 Sep 2020 16:23:58 |
| User entered 'hypetension'   | Son Do (b) (4)                  | 17 Sep 2020 16:23:27 |

US3642217

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:16:22

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.          |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                             | 02 May 2021 07:09:50 |
| Data hard locked.          |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.        |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.          |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:55 |
| User entered 'UN UNK 1985' | Son Do (b) (4)              | 17 Sep 2020 16:23:27 |

US3642217

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:16:22

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:55 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:23:27 |

US3642217

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:55 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:23:27 |

US3642217

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:55 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:23:27 |



US3642217

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:55 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:23:27 |

US3642217

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 1985' | System           | 17 Sep 2020 16:23:27 |

US3642217

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '1985' | System           | 17 Sep 2020 16:23:27 |

US3642217

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 17 Sep 2020 16:23:27 |

US3642217

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 17 Sep 2020 16:23:27 |

US3642217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                | 03 May 2021 19:16:41 |
| Data hard locked.  |                                 | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                 | 02 May 2021 07:09:50 |
| Data hard locked.  |                                 | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                 | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                 | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)         | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 08 Dec 2020 18:04:58 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:24:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:24:38 |
| Data point term sent to Coder  | System                          | 17 Sep 2020 16:23:58 |
| User entered 'type 2 diabetes'   | Son Do (b) (4)                  | 17 Sep 2020 16:23:42 |

US3642217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.          |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                             | 02 May 2021 07:09:50 |
| Data hard locked.          |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.        |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.          |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:58 |
| User entered 'UN UNK 2016' | Son Do (b) (4)              | 17 Sep 2020 16:23:42 |

US3642217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:58 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:23:42 |



US3642217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:58 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:23:42 |

US3642217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:58 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:23:42 |

US3642217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:04:58 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:23:42 |

US3642217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 2016' | System           | 17 Sep 2020 16:23:42 |

US3642217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2016' | System           | 17 Sep 2020 16:23:42 |

US3642217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 17 Sep 2020 16:23:42 |

US3642217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 17 Sep 2020 16:23:42 |

US3642217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:16:22

Condition

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                | 03 May 2021 19:16:41 |
| Data hard locked.  |                                 | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                 | 02 May 2021 07:09:50 |
| Data hard locked.  |                                 | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                 | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                 | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)         | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 08 Dec 2020 18:05:01 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' canceled (Site from DM).    |                                 | 08 Nov 2020 18:13:04 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM). |                                 | 21 Oct 2020 16:19:15 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.                                | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:24:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:24:39 |
| Data point term sent to Coder  | System                          | 17 Sep 2020 16:23:58 |
| User entered 'emphysema'   | Son Do (b) (4)                  | 17 Sep 2020 16:23:55 |



US3642217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.          |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                             | 02 May 2021 07:09:50 |
| Data hard locked.          |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.        |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.          |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:05:01 |
| User entered 'UN UNK 2018' | Son Do (b) (4)              | 17 Sep 2020 16:23:55 |

US3642217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:16:22

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:05:01 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:23:55 |

US3642217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:05:01 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:23:55 |

US3642217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:05:01 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:23:55 |

US3642217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:05:01 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:23:55 |

US3642217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 2018' | System           | 17 Sep 2020 16:23:55 |

US3642217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2018' | System           | 17 Sep 2020 16:23:55 |

US3642217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 17 Sep 2020 16:23:55 |



US3642217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 17 Sep 2020 16:23:55 |

US3642217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.  |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.  |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:03 |
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Vulvovaginal disorders (excl infections and inflammations), HLT: Vulvovaginal signs and symptoms, PT: Vulvovaginal dryness, LLT: Vaginal dryness - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 26 Sep 2020 21:04:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)   | 26 Sep 2020 21:04:50 |
| Data point term sent to Coder  | System                            | 26 Sep 2020 21:04:35 |
| User entered 'vaginal dryness'   | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:04:17 |

US3642217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.          |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                                   | 02 May 2021 07:09:50 |
| Data hard locked.          |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.        |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.          |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:03 |
| User entered 'UN May 2020' | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:04:17 |

US3642217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:03 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:04:17 |

US3642217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:03 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:04:17 |

US3642217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:03 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:04:17 |

US3642217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:03 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:04:17 |

US3642217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'May 2020' | System           | 26 Sep 2020 21:04:17 |



US3642217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2020' | System           | 26 Sep 2020 21:04:17 |

US3642217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 26 Sep 2020 21:04:17 |

US3642217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 26 Sep 2020 21:04:17 |

US3642217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.  |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.  |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:06 |
| 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)<br>(b) (4)   | 26 Sep 2020 21:06:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)   | 26 Sep 2020 21:06:50 |
| Data point term sent to Coder  | System                            | 26 Sep 2020 21:05:36 |
| User entered 'seasonal allergies'  | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:04:39 |

US3642217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.          |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                                   | 02 May 2021 07:09:50 |
| Data hard locked.          |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.        |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.          |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:06 |
| User entered 'UN UNK 2019' | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:04:39 |

US3642217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:06 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:04:39 |

US3642217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:06 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:04:39 |

US3642217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:06 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:04:39 |



US3642217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:06 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:04:39 |

US3642217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 2019' | System           | 26 Sep 2020 21:04:39 |

US3642217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2019' | System           | 26 Sep 2020 21:04:39 |

US3642217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 26 Sep 2020 21:04:39 |

US3642217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 26 Sep 2020 21:04:39 |

US3642217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard unlocked.   | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.   |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.   |                                   | 02 May 2021 07:09:50 |
| Data hard locked.   |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.   |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.   | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:09 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 26 Sep 2020 21:06:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)   | 26 Sep 2020 21:06:50 |
| Data point term sent to Coder   | System                            | 26 Sep 2020 21:05:36 |
| User entered 'anxiety'  | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:05:00 |

US3642217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.          |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                                   | 02 May 2021 07:09:50 |
| Data hard locked.          |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.        |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.          |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:09 |
| User entered 'UN UNK 2018' | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:05:00 |

US3642217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:09 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:05:00 |



US3642217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.  |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.  |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:09 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 26 Sep 2020 21:05:05 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 26 Sep 2020 21:05:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:05:05 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 26 Sep 2020 21:05:00 |
| User entered empty.  | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:05:00 |

US3642217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:09 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:05:00 |

US3642217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:09 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 26 Sep 2020 21:05:00 |

US3642217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 2018' | System           | 26 Sep 2020 21:05:00 |

US3642217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2018' | System           | 26 Sep 2020 21:05:00 |

US3642217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 26 Sep 2020 21:05:00 |

US3642217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 26 Sep 2020 21:05:00 |

US3642217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard unlocked.   | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.   |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.   |                                   | 02 May 2021 07:09:50 |
| Data hard locked.   |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.   |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.   | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:13 |
| User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 15 Oct 2020 04:35:22 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)   | 15 Oct 2020 04:35:22 |
| Data point term sent to Coder   | System                            | 15 Oct 2020 04:34:35 |
| User entered 'post menopausal'  | Megan Loughran (b) (4)<br>(b) (4) | 15 Oct 2020 04:34:07 |



US3642217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard unlocked.   | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.   |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.   |                                   | 02 May 2021 07:09:50 |
| Data hard locked.   |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.   |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.   | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:13 |
| User entered 'UN UNK 1985' reason for change:<br>Data Entry Error | Son Do (b) (4)                    | 12 Nov 2020 16:04:15 |
| User entered empty.   | Megan Loughran (b) (4)<br>(b) (4) | 15 Oct 2020 04:34:07 |

US3642217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.                                  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.                                    |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.                                  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.                                    |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.                                  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.                                    |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.                            | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                                  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:13 |
| User entered '0' reason for change: Data Entry Error | Son Do (b) (4)                    | 12 Nov 2020 16:04:15 |
| User entered '1'                                     | Megan Loughran (b) (4)<br>(b) (4) | 15 Oct 2020 04:34:07 |

US3642217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:13 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 15 Oct 2020 04:34:07 |

US3642217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:13 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 15 Oct 2020 04:34:07 |

US3642217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:13 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 15 Oct 2020 04:34:07 |

US3642217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 1985' | System           | 12 Nov 2020 16:04:15 |
| User entered empty.     | System           | 15 Oct 2020 04:34:07 |

US3642217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:16:22

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '1985' | System           | 12 Nov 2020 16:04:15 |
| User entered empty. | System           | 15 Oct 2020 04:34:07 |

US3642217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 15 Oct 2020 04:34:07 |



US3642217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 15 Oct 2020 04:34:07 |

US3642217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.  |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.  |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:18 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)   | 24 Nov 2020 23:12:59 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4)   | 24 Nov 2020 23:12:59 |
| Data point term sent to Coder  | System                            | 24 Nov 2020 22:57:35 |
| User entered 'hip pain right'  | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:56:59 |

US3642217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.          |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                                   | 02 May 2021 07:09:50 |
| Data hard locked.          |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.        |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.          |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:18 |
| User entered 'un May 2020' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:56:59 |

US3642217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:18 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:56:59 |

US3642217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:18 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:56:59 |

US3642217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:18 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:56:59 |

US3642217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.         |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                                   | 02 May 2021 07:09:50 |
| Data hard locked.         |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:18 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:56:59 |

US3642217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'May 2020' | System           | 24 Nov 2020 22:56:59 |



US3642217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2020' | System           | 24 Nov 2020 22:56:59 |

US3642217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 24 Nov 2020 22:56:59 |

US3642217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 24 Nov 2020 22:56:59 |

US3642217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:16:22

Condition

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.  |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.  |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |                                   | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| User closed query 'Per MM, please include the underlying condition that led to the procedure. ' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 12:26:49 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Peripheral artery bypass, LLT: Femoral artery bypass - version MedDRA\\23.0.               | Coder Import (b) (4)<br>(b) (4)   | 05 Apr 2021 22:40:30 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)   | 05 Apr 2021 22:40:30 |
| Data point term sent to Coder  | System                            | 05 Apr 2021 22:40:03 |
| Query 'Per MM, please include the underlying condition that led to the procedure. ' answered with 'this has been added to line 17 - arterial stenosis. ' (Site from DM).   | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:39:26 |
| User entered 'FEMORAL BYPASS SURGERY' reason for change: Data Entry Error  | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:39:11 |
| User closed query 'CDM coding: Please split the reported term FEMORAL BYPASS SURGERY (ARTERIAL STENOSIS) on two separate loglines to capture coding for both the terms. Example: 1) FEMORAL BYPASS SURGERY and 2) ARTERIAL STENOSIS' (Site from System). | System                            | 05 Apr 2021 22:39:05 |

US3642217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:16:22

Condition

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Query 'CDM coding: Please split the reported term FEMORAL BYPASS SURGERY (ARTERIAL STENOSIS) on two separate loglines to capture coding for both the terms. Example: 1) FEMORAL BYPASS SURGERY and 2) ARTERIAL STENOSIS' answered with 'arterial stenosis has been added to line 17' (Site from System). | Megan Loughran (b) (4)   | 05 Apr 2021 22:39:05 |
| Data point term sent to Coder  | System                   | 05 Apr 2021 22:39:02 |
| Signature has been broken.   | Megan Loughran (b) (4)   | 05 Apr 2021 22:38:24 |
| User entered 'FEMORAL BYPASS SURGERY due to ARTERIAL STENOSIS' reason for change: Data Entry Error   | Megan Loughran (b) (4)   | 05 Apr 2021 22:38:24 |
| User opened query 'Per MM, please include the underlying condition that led to the procedure.' (Site from DM).   | (b) (4), (b) (6)         | 29 Mar 2021 16:30:49 |
| User opened query 'CDM coding: Please split the reported term FEMORAL BYPASS SURGERY (ARTERIAL STENOSIS) on two separate loglines to capture coding for both the terms. Example: 1) FEMORAL BYPASS SURGERY and 2) ARTERIAL STENOSIS' (Site from System).   | Coder Import (b) (4)     | 22 Mar 2021 12:51:46 |
| User signature succeeded.  | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| User closed query 'Per MM: Please include the underlying condition that led to the procedure.' (Site from DM).   | (b) (4), (b) (6)         | 23 Feb 2021 04:58:44 |
| Data point term sent to Coder  | System                   | 22 Feb 2021 20:18:13 |
| Query 'Per MM: Please include the underlying condition that led to the procedure.' answered with 'underlying condition now included ' (Site from DM).  | Colleen McLellan (b) (4) | 22 Feb 2021 20:18:01 |
| Coding entries removed.  | Colleen McLellan (b) (4) | 22 Feb 2021 20:17:47 |
| User entered 'FEMORAL BYPASS SURGERY (arterial stenosis)' reason for change: Data Entry Error  | Colleen McLellan (b) (4) | 22 Feb 2021 20:17:47 |
| User opened query 'Per MM: Please include the underlying condition that led to the procedure.' (Site from DM).   | (b) (4), (b) (6)         | 01 Feb 2021 19:04:34 |

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).                           | (b) (4), (b) (6)       | 25 Jan 2021 16:13:01 |
| Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'added' (Site from DM).                 | Megan Loughran (b) (4) | 22 Jan 2021 21:23:10 |
| User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).                           | (b) (4), (b) (6)       | 13 Jan 2021 09:20:36 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Peripheral artery bypass, LLT: Femoral artery bypass - version MedDRA\\23.0. | Coder Import (b) (4)   | 15 Dec 2020 13:00:01 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)   | 15 Dec 2020 13:00:01 |
| Data point term sent to Coder  | System                 | 14 Dec 2020 19:10:39 |
| User entered 'femoral bypass surgery'  | Megan Loughran (b) (4) | 14 Dec 2020 19:09:55 |
| DataPoint activated with code reason code Data required.   | Megan Loughran (b) (4) | 14 Dec 2020 19:09:34 |
| DataPoint inactivated with code reason code Data not required.   | Megan Loughran (b) (4) | 24 Nov 2020 23:04:45 |

US3642217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.  |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.  |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |                                   | 20 Apr 2021 15:25:30 |
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| User entered 'un UNK 2015'                                     | (b) (4)<br>Megan Loughran (b) (4) | 14 Dec 2020 19:09:55 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Megan Loughran (b) (4) | 14 Dec 2020 19:09:34 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:04:45 |

US3642217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.  |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.  |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |                                   | 20 Apr 2021 15:25:30 |
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| User entered '0'   | (b) (4)<br>Megan Loughran (b) (4) | 14 Dec 2020 19:09:55 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Megan Loughran (b) (4) | 14 Dec 2020 19:09:34 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:04:45 |



US3642217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.  |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.  |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |                                   | 20 Apr 2021 15:25:30 |
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| User entered 'No (N)'  | (b) (4)<br>Megan Loughran (b) (4) | 14 Dec 2020 19:09:55 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Megan Loughran (b) (4) | 14 Dec 2020 19:09:34 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:04:45 |

US3642217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.  |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.  |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |                                   | 20 Apr 2021 15:25:30 |
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| User entered 'un UNK 2015'                                     | (b) (4)<br>Megan Loughran (b) (4) | 14 Dec 2020 19:09:55 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Megan Loughran (b) (4) | 14 Dec 2020 19:09:34 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:04:45 |

US3642217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.  |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.  |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |                                   | 20 Apr 2021 15:25:30 |
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| User entered '0'   | (b) (4)<br>Megan Loughran (b) (4) | 14 Dec 2020 19:09:55 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Megan Loughran (b) (4) | 14 Dec 2020 19:09:34 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:04:45 |

US3642217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:16:22

Start Month and Year (derived)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)       | 03 May 2021 19:16:41 |
| Data hard locked.  |                        | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                        | 02 May 2021 07:09:50 |
| Data hard locked.  |                        | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                        | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                        | 28 Apr 2021 19:15:41 |
| User entered 'Jan 2015'  | System                 | 14 Dec 2020 19:09:55 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4) | 14 Dec 2020 19:09:34 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4) | 24 Nov 2020 23:04:45 |

US3642217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:16:22

Start Year (derived)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)       | 03 May 2021 19:16:41 |
| Data hard locked.  |                        | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                        | 02 May 2021 07:09:50 |
| Data hard locked.  |                        | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                        | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                        | 28 Apr 2021 19:15:41 |
| User entered '2015'  | System                 | 14 Dec 2020 19:09:55 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4) | 14 Dec 2020 19:09:34 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4) | 24 Nov 2020 23:04:45 |

US3642217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)       | 03 May 2021 19:16:41 |
| Data hard locked.  |                        | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                        | 02 May 2021 07:09:50 |
| Data hard locked.  |                        | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                        | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                        | 28 Apr 2021 19:15:41 |
| User entered 'Jan 2015'  | System                 | 14 Dec 2020 19:09:55 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4) | 14 Dec 2020 19:09:34 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4) | 24 Nov 2020 23:04:45 |

US3642217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)       | 03 May 2021 19:16:41 |
| Data hard locked.  |                        | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                        | 02 May 2021 07:09:50 |
| Data hard locked.  |                        | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                        | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                        | 28 Apr 2021 19:15:41 |
| User entered '2015'  | System                 | 14 Dec 2020 19:09:55 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4) | 14 Dec 2020 19:09:34 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4) | 24 Nov 2020 23:04:45 |

US3642217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                           | 03 May 2021 19:16:41 |
| Data hard locked.  |  | 02 May 2021 22:51:58 |
| Data hard unlocked.  |  | 02 May 2021 07:09:50 |
| Data hard locked.  |  | 01 May 2021 20:11:07 |
| Data hard unlocked.  |  | 30 Apr 2021 08:38:49 |
| Data hard locked.  |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                    | 06 Mar 2021 01:50:28 |
| User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 22 Jan 2021 21:24:06 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)            | 22 Jan 2021 21:24:06 |
| Data point term sent to Coder  | System                                     | 22 Jan 2021 21:23:29 |
| User entered 'coronary artery disease'   | Megan Loughran (b) (4)<br>(b) (4)          | 22 Jan 2021 21:23:03 |



US3642217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.          |  | 02 May 2021 22:51:58 |
| Data hard unlocked.        |  | 02 May 2021 07:09:50 |
| Data hard locked.          |  | 01 May 2021 20:11:07 |
| Data hard unlocked.        |  | 30 Apr 2021 08:38:49 |
| Data hard locked.          |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.        |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                      | 06 Mar 2021 01:50:28 |
| User entered 'un UNK 2015' | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 22 Jan 2021 21:23:03 |

US3642217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 06 Mar 2021 01:50:28 |
| User entered '0'          | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 22 Jan 2021 21:23:03 |

US3642217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 06 Mar 2021 01:50:28 |
| User entered 'Yes (Y)'    | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 22 Jan 2021 21:23:03 |

US3642217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 06 Mar 2021 01:50:28 |
| User entered empty.       | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 22 Jan 2021 21:23:03 |

US3642217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 06 Mar 2021 01:50:28 |
| User entered '0'          | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 22 Jan 2021 21:23:03 |

US3642217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 2015' | System           | 22 Jan 2021 21:23:03 |

US3642217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2015' | System           | 22 Jan 2021 21:23:03 |

US3642217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 22 Jan 2021 21:23:03 |



US3642217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 22 Jan 2021 21:23:03 |

US3642217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                           | 03 May 2021 19:16:41 |
| Data hard locked.  |  | 02 May 2021 22:51:58 |
| Data hard unlocked.  |  | 02 May 2021 07:09:50 |
| Data hard locked.  |  | 01 May 2021 20:11:07 |
| Data hard unlocked.  |  | 30 Apr 2021 08:38:49 |
| Data hard locked.  |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                    | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\23.0. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 06 Apr 2021 09:52:54 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4)            | 06 Apr 2021 09:52:54 |
| Data point term sent to Coder  | System                                     | 05 Apr 2021 22:29:53 |
| User entered 'chronic kidney disease stage 3a'   | Megan Loughran (b) (4)<br>(b) (4)          | 05 Apr 2021 22:29:18 |

US3642217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:29:18 |

US3642217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)        | 03 May 2021 19:16:41 |
|                           |                         |                      |
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 22:51:58 |
|                           |                         |                      |
| Data hard unlocked.       | (b) (4), (b) (6)        | 02 May 2021 07:09:50 |
|                           |                         |                      |
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 20:11:07 |
|                           |                         |                      |
| Data hard unlocked.       | (b) (4), (b) (6)        | 30 Apr 2021 08:38:49 |
|                           |                         |                      |
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 19:15:41 |
|                           |                         |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:25:30 |
|                           |                         |                      |
| User signature succeeded. | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
|                           | (b) (4)                 |                      |
| User entered 'I'          | Megan Loughran (b) (4)  | 05 Apr 2021 22:29:18 |
|                           | (b) (4)                 |                      |

US3642217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered 'Yes (Y)'    | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:29:18 |

US3642217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:29:18 |

US3642217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:29:18 |

US3642217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 05 Apr 2021 22:29:18 |



US3642217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 05 Apr 2021 22:29:18 |

US3642217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 05 Apr 2021 22:29:18 |

US3642217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 05 Apr 2021 22:29:18 |

US3642217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.  |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.  |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |                                   | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament rupture, LLT: Anterior cruciate ligament tear - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)   | 06 Apr 2021 12:14:53 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)   | 06 Apr 2021 12:14:53 |
| Data point term sent to Coder  | System                            | 05 Apr 2021 22:29:53 |
| User entered 'chronic tear of acl'   | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:29:50 |

US3642217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:29:50 |

US3642217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered 'I'          | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:29:50 |

US3642217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered 'Yes (Y)'    | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:29:50 |

US3642217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:29:50 |



US3642217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:29:50 |

US3642217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 05 Apr 2021 22:29:50 |

US3642217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:16:22

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 05 Apr 2021 22:29:50 |

US3642217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 05 Apr 2021 22:29:50 |

US3642217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 05 Apr 2021 22:29:50 |

US3642217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.  |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:50 |
| Data hard locked.  |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |                                   | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary abnormalities, PT: Microalbuminuria, LLT: Microalbuminuria - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)   | 05 Apr 2021 22:31:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)   | 05 Apr 2021 22:31:41 |
| Data point term sent to Coder  | System                            | 05 Apr 2021 22:30:56 |
| User entered 'microalbuminuria'  | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:30:24 |

US3642217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
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| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:30:24 |

US3642217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
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US3642217

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Form: Medical History (14)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
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| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered 'Yes (Y)'    | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:30:24 |

US3642217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
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| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
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| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:30:24 |

US3642217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
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| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
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Form: Medical History (14)

Generated On: 10 Jun 2021 09:16:22

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| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
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[Stop Year \(derived\)](#)

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Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| Data hard unlocked.   | (b) (4), (b) (6)                           | 03 May 2021 19:16:41 |
| Data hard locked.   |  | 02 May 2021 22:51:58 |
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| Data hard unlocked.   |  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.   |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.   | Stephen Spector (b) (4)                    | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Onychomycosis, LLT: Onychomycosis - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 05 Apr 2021 22:31:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)            | 05 Apr 2021 22:31:41 |
| Data point term sent to Coder   | System                                     | 05 Apr 2021 22:30:54 |
| User entered 'onychomycosis'  | Megan Loughran (b) (4)<br>(b) (4)          | 05 Apr 2021 22:30:43 |



US3642217

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
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| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:30:43 |

US3642217

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
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| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered 'I'          | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:30:43 |

US3642217

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[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
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| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
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| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
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| Audit                     | User   | Time (GMT)           |
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| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
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[Start Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
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| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
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Form: Medical History (15)

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| Audit               | User             | Time (GMT)           |
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| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
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[Condition](#)

| Audit   | User                                       | Time (GMT)           |
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| Data hard unlocked.   | (b) (4), (b) (6)                           | 03 May 2021 19:16:41 |
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| DataPoint Verified.   |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.   | Stephen Spector (b) (4)                    | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Lumbar radiculopathy, LLT: Lumbar radiculopathy - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 05 Apr 2021 22:33:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)            | 05 Apr 2021 22:33:42 |
| Data point term sent to Coder   | System                                     | 05 Apr 2021 22:32:57 |
| User entered 'lumbar radiculopathy'   | Megan Loughran (b) (4)<br>(b) (4)          | 05 Apr 2021 22:32:11 |

US3642217

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| Audit                     | User   | Time (GMT)           |
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| Data hard unlocked.  |                                 | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                 | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |                                 | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)         | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Arterial stenosis, LLT: Arterial stenosis - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 05 Apr 2021 22:39:29 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)            | 05 Apr 2021 22:39:29 |
| Data point term sent to Coder  | System                          | 05 Apr 2021 22:39:02 |
| User entered 'arterial stenosis'   | Megan Loughran (b) (4)          | 05 Apr 2021 22:38:02 |
|  | (b) (4)                         |                      |

US3642217

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.          |  | 02 May 2021 22:51:58 |
| Data hard unlocked.        |  | 02 May 2021 07:09:50 |
| Data hard locked.          |  | 01 May 2021 20:11:07 |
| Data hard unlocked.        |  | 30 Apr 2021 08:38:49 |
| Data hard locked.          |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.        |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered 'un UNK 2015' | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:38:02 |

US3642217

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:38:02 |

US3642217

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered 'Yes (Y)'    | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:38:02 |

US3642217

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:38:02 |



US3642217

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 22:38:02 |

US3642217

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 2015' | System           | 05 Apr 2021 22:38:02 |

US3642217

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2015' | System           | 05 Apr 2021 22:38:02 |

US3642217

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 05 Apr 2021 22:38:02 |

US3642217

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 05 Apr 2021 22:38:02 |

US3642217

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                    | 03 May 2021 19:16:41 |
| Data hard locked.  |                                     | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                     | 02 May 2021 07:09:50 |
| Data hard locked.  |                                     | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                     | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                     | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |                                     | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Pulmonary mass, LLT: Lung nodule - version MedDRA\23.0. | (b) (4)<br>Coder Import (b) (4)     | 07 Apr 2021 20:23:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)                | 07 Apr 2021 20:23:18 |
| Data point term sent to Coder  | System                              | 07 Apr 2021 20:21:29 |
| User entered 'pulmonary nodules'   | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:21:17 |

US3642217

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.          |  | 02 May 2021 22:51:58 |
| Data hard unlocked.        |  | 02 May 2021 07:09:50 |
| Data hard locked.          |  | 01 May 2021 20:11:07 |
| Data hard unlocked.        |  | 30 Apr 2021 08:38:49 |
| Data hard locked.          |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.        |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'UN Sep 2014' | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:21:17 |

US3642217

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:21:17 |



US3642217

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'Yes (Y)'    | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:21:17 |

US3642217

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:21:17 |

US3642217

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:21:17 |

US3642217

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Sep 2014' | System           | 07 Apr 2021 20:21:17 |

US3642217

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:16:22

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2014' | System           | 07 Apr 2021 20:21:17 |

US3642217

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:21:17 |

US3642217

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:21:17 |

US3642217

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard unlocked.   | (b) (4), (b) (6)                | 03 May 2021 19:16:41 |
| Data hard locked.   |                                 | 02 May 2021 22:51:58 |
| Data hard unlocked.   |                                 | 02 May 2021 07:09:50 |
| Data hard locked.   |                                 | 01 May 2021 20:11:07 |
| Data hard unlocked.   |                                 | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                                 | 28 Apr 2021 19:15:41 |
| DataPoint Verified.   |                                 | 20 Apr 2021 15:25:30 |
| User signature succeeded.   | Stephen Spector (b) (4)         | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Vascular disorders, HLT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Peripheral vascular disorder, LLT: Peripheral vascular disease - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 07 Apr 2021 20:23:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)            | 07 Apr 2021 20:23:18 |
| Data point term sent to Coder   | System                          | 07 Apr 2021 20:22:32 |
| User entered 'peripheral vascular disease'  | Colleen McLellan (b) (4)        | 07 Apr 2021 20:21:43 |
|   | (b) (4)                         |                      |



US3642217

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.          |  | 02 May 2021 22:51:58 |
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| Data hard locked.          |  | 01 May 2021 20:11:07 |
| Data hard unlocked.        |  | 30 Apr 2021 08:38:49 |
| Data hard locked.          |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.        |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'un UNK 2014' | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:21:43 |

US3642217

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:21:43 |

US3642217

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'Yes (Y)'    | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:21:43 |

US3642217

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
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| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:21:43 |

US3642217

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:21:43 |

US3642217

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 2014' | System           | 07 Apr 2021 20:21:43 |

US3642217

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2014' | System           | 07 Apr 2021 20:21:43 |

US3642217

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:21:43 |



US3642217

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:21:43 |

US3642217

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                           | 03 May 2021 19:16:41 |
| Data hard locked.  |  | 02 May 2021 22:51:58 |
| Data hard unlocked.  |  | 02 May 2021 07:09:50 |
| Data hard locked.  |  | 01 May 2021 20:11:07 |
| Data hard unlocked.  |  | 30 Apr 2021 08:38:49 |
| Data hard locked.  |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                    | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic arteriosclerosis, LLT: Atherosclerosis of aorta - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 07 Apr 2021 20:23:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)            | 07 Apr 2021 20:23:18 |
| Data point term sent to Coder  | System                                     | 07 Apr 2021 20:22:31 |
| User entered 'atherosclerosis of aorta'  | Colleen McLellan (b) (4)<br>(b) (4)        | 07 Apr 2021 20:22:15 |

US3642217

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.          |  | 02 May 2021 22:51:58 |
| Data hard unlocked.        |  | 02 May 2021 07:09:50 |
| Data hard locked.          |  | 01 May 2021 20:11:07 |
| Data hard unlocked.        |  | 30 Apr 2021 08:38:49 |
| Data hard locked.          |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.        |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                        | 08 May 2021 23:59:42 |
| User entered 'un Aug 2016' | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:15 |

US3642217

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:15 |

US3642217

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'Yes (Y)'    | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:15 |

US3642217

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:15 |

US3642217

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:15 |

US3642217

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Aug 2016' | System           | 07 Apr 2021 20:22:15 |



US3642217

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:16:22

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2016' | System           | 07 Apr 2021 20:22:15 |

US3642217

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:22:15 |

US3642217

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:22:15 |

US3642217

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                           | 03 May 2021 19:16:41 |
| Data hard locked.  |  | 02 May 2021 22:51:58 |
| Data hard unlocked.  |  | 02 May 2021 07:09:50 |
| Data hard locked.  |  | 01 May 2021 20:11:07 |
| Data hard unlocked.  |  | 30 Apr 2021 08:38:49 |
| Data hard locked.  |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                    | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 07 Apr 2021 20:23:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4)            | 07 Apr 2021 20:23:18 |
| Data point term sent to Coder  | System                                     | 07 Apr 2021 20:22:33 |
| User entered 'copd'  | Colleen McLellan (b) (4)<br>(b) (4)        | 07 Apr 2021 20:22:32 |

US3642217

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.          |  | 02 May 2021 22:51:58 |
| Data hard unlocked.        |  | 02 May 2021 07:09:50 |
| Data hard locked.          |  | 01 May 2021 20:11:07 |
| Data hard unlocked.        |  | 30 Apr 2021 08:38:49 |
| Data hard locked.          |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.        |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'un UNK 2015' | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:32 |

US3642217

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 May 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:32 |

US3642217

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'Yes (Y)'    | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:32 |

US3642217

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:32 |



US3642217

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:32 |

US3642217

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 2015' | System           | 07 Apr 2021 20:22:32 |

US3642217

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:16:22

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2015' | System           | 07 Apr 2021 20:22:32 |

US3642217

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:22:32 |

US3642217

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:22:32 |

US3642217

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                           | 03 May 2021 19:16:41 |
| Data hard locked.  |  | 02 May 2021 22:51:58 |
| Data hard unlocked.  |  | 02 May 2021 07:09:50 |
| Data hard locked.  |  | 01 May 2021 20:11:07 |
| Data hard unlocked.  |  | 30 Apr 2021 08:38:49 |
| Data hard locked.  |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                    | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Cardiac disorders,<br>HLGT: Myocardial disorders, HLT:<br>Cardiomyopathies, PT: Cardiomyopathy, LLT:<br>Cardiomyopathy - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 07 Apr 2021 20:24:22 |
| User coded data point as Term Coded data point by<br>User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)            | 07 Apr 2021 20:24:22 |
| Data point term sent to Coder<br>System  | System                                     | 07 Apr 2021 20:23:34 |
| User entered 'cardiomyopathy'  | Colleen McLellan (b) (4)<br>(b) (4)        | 07 Apr 2021 20:22:59 |

US3642217

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.          |  | 02 May 2021 22:51:58 |
| Data hard unlocked.        |  | 02 May 2021 07:09:50 |
| Data hard locked.          |  | 01 May 2021 20:11:07 |
| Data hard unlocked.        |  | 30 Apr 2021 08:38:49 |
| Data hard locked.          |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.        |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'un Sep 2017' | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:59 |

US3642217

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:59 |



US3642217

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'Yes (Y)'    | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:59 |

US3642217

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:59 |

US3642217

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:22:59 |

US3642217

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Sep 2017' | System           | 07 Apr 2021 20:22:59 |

US3642217

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2017' | System           | 07 Apr 2021 20:22:59 |

US3642217

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:22:59 |

US3642217

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:22:59 |

US3642217

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| Data hard unlocked.   | (b) (4), (b) (6)                           | 03 May 2021 19:16:41 |
| Data hard locked.   |  | 02 May 2021 22:51:58 |
| Data hard unlocked.   |  | 02 May 2021 07:09:50 |
| Data hard locked.   |  | 01 May 2021 20:11:07 |
| Data hard unlocked.   |  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.   |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.   | Stephen Spector (b) (4)                    | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Bundle branch block left, LLT: Left bundle branch block - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 07 Apr 2021 20:24:22 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)            | 07 Apr 2021 20:24:22 |
| Data point term sent to Coder   | System                                     | 07 Apr 2021 20:23:34 |
| User entered 'left bundle branch block'   | Colleen McLellan (b) (4)<br>(b) (4)        | 07 Apr 2021 20:23:21 |



US3642217

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.          |  | 02 May 2021 22:51:58 |
| Data hard unlocked.        |  | 02 May 2021 07:09:50 |
| Data hard locked.          |  | 01 May 2021 20:11:07 |
| Data hard unlocked.        |  | 30 Apr 2021 08:38:49 |
| Data hard locked.          |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.        |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'un UNK 2016' | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:23:21 |

US3642217

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:23:21 |

US3642217

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'Yes (Y)'    | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:23:21 |

US3642217

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:23:21 |

US3642217

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:23:21 |

US3642217

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 2016' | System           | 07 Apr 2021 20:23:21 |

US3642217

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2016' | System           | 07 Apr 2021 20:23:21 |

US3642217

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:23:21 |



US3642217

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:23:21 |

US3642217

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard unlocked.  | (b) (4), (b) (6)                    | 03 May 2021 19:16:41 |
| Data hard locked.  |                                     | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                     | 02 May 2021 07:09:50 |
| Data hard locked.  |                                     | 01 May 2021 20:11:07 |
| Data hard unlocked.  |                                     | 30 Apr 2021 08:38:49 |
| Data hard locked.  |                                     | 28 Apr 2021 19:15:41 |
| DataPoint Verified.  |                                     | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Cardiac disorders, HLT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Heart failure with preserved ejection fraction - version MedDRA\23.0. | (b) (4)<br>Coder Import (b) (4)     | 08 Apr 2021 06:10:57 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4)     | 08 Apr 2021 06:10:57 |
| Data point term sent to Coder  | System                              | 07 Apr 2021 20:24:35 |
| User entered 'heart failure with a normal ejection fraction'   | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:24:00 |

US3642217

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.          |  | 02 May 2021 22:51:58 |
| Data hard unlocked.        |  | 02 May 2021 07:09:50 |
| Data hard locked.          |  | 01 May 2021 20:11:07 |
| Data hard unlocked.        |  | 30 Apr 2021 08:38:49 |
| Data hard locked.          |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.        |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'un Aug 2019' | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:24:00 |

US3642217

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:24:00 |

US3642217

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered 'Yes (Y)'    | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:24:00 |

US3642217

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered empty.       | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:24:00 |

US3642217

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                               | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 20:24:00 |

US3642217

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Aug 2019' | System           | 07 Apr 2021 20:24:00 |



US3642217

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:16:22

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '2019' | System           | 07 Apr 2021 20:24:00 |

US3642217

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:24:00 |

US3642217

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 07 Apr 2021 20:24:00 |

US3642217

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard unlocked.   | (b) (4), (b) (6)                  | 03 May 2021 19:16:41 |
| Data hard locked.   |                                   | 02 May 2021 22:51:58 |
| Data hard unlocked.   |                                   | 02 May 2021 07:09:50 |
| Data hard locked.   |                                   | 01 May 2021 20:11:07 |
| Data hard unlocked.   |                                   | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                                   | 28 Apr 2021 19:15:41 |
| DataPoint Verified.   |                                   | 20 Apr 2021 15:25:30 |
| User signature succeeded.   | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)   | 08 Apr 2021 06:16:08 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)   | 08 Apr 2021 06:16:08 |
| Data point term sent to Coder   | System                            | 07 Apr 2021 20:39:05 |
| User entered 'juvederm cosmetic injection'  | Megan Loughran (b) (4)<br>(b) (4) | 07 Apr 2021 20:38:25 |

US3642217

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.          |  | 02 May 2021 22:51:58 |
| Data hard unlocked.        |  | 02 May 2021 07:09:50 |
| Data hard locked.          |  | 01 May 2021 20:11:07 |
| Data hard unlocked.        |  | 30 Apr 2021 08:38:49 |
| Data hard locked.          |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.        |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered 'un UNK 1997' | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 07 Apr 2021 20:38:25 |

US3642217

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 07 Apr 2021 20:38:25 |

US3642217

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered 'No (N)'     | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 07 Apr 2021 20:38:25 |

US3642217

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard unlocked.        | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.          |  | 02 May 2021 22:51:58 |
| Data hard unlocked.        |  | 02 May 2021 07:09:50 |
| Data hard locked.          |  | 01 May 2021 20:11:07 |
| Data hard unlocked.        |  | 30 Apr 2021 08:38:49 |
| Data hard locked.          |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.        |  | 20 Apr 2021 15:25:30 |
| User signature succeeded.  | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered 'un UNK 1997' | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 07 Apr 2021 20:38:25 |



US3642217

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)                             | 03 May 2021 19:16:41 |
| Data hard locked.         |  | 02 May 2021 22:51:58 |
| Data hard unlocked.       |  | 02 May 2021 07:09:50 |
| Data hard locked.         |  | 01 May 2021 20:11:07 |
| Data hard unlocked.       |  | 30 Apr 2021 08:38:49 |
| Data hard locked.         |  | 28 Apr 2021 19:15:41 |
| DataPoint Verified.       |  | 20 Apr 2021 15:25:30 |
| User signature succeeded. | Stephen Spector (b) (4)                      | 08 Apr 2021 23:59:42 |
| User entered '0'          | (b) (4)<br>Megan Loughran (b) (4)<br>(b) (4) | 07 Apr 2021 20:38:25 |

US3642217

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 1997' | System           | 07 Apr 2021 20:38:25 |

US3642217

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '1997' | System           | 07 Apr 2021 20:38:25 |

US3642217

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard unlocked.     | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.       |                  | 02 May 2021 22:51:58 |
| Data hard unlocked.     |                  | 02 May 2021 07:09:50 |
| Data hard locked.       |                  | 01 May 2021 20:11:07 |
| Data hard unlocked.     |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.       |                  | 28 Apr 2021 19:15:41 |
| User entered 'Jan 1997' | System           | 07 Apr 2021 20:38:25 |

US3642217

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered '1997' | System           | 07 Apr 2021 20:38:25 |

US3642217

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:16:22

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard unlocked.   | (b) (4), (b) (6)                | 03 May 2021 19:16:41 |
| Data hard locked.   |                                 | 02 May 2021 22:51:58 |
| Data hard unlocked.   |                                 | 02 May 2021 07:09:50 |
| Data hard locked.   |                                 | 01 May 2021 20:11:07 |
| Data hard unlocked.   |                                 | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                                 | 28 Apr 2021 19:15:41 |
| User signature succeeded.   | Stephen Spector (b) (4)         | 23 Apr 2021 20:51:21 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 22 Apr 2021 18:08:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)            | 22 Apr 2021 18:08:54 |
| Data point term sent to Coder   | System                          | 22 Apr 2021 18:07:43 |
| User entered 'CHRONIC BACK PAIN'  | (b) (4), (b) (6)                | 22 Apr 2021 18:07:10 |

US3642217

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 23 Apr 2021 20:51:21 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Apr 2021 18:07:10 |

US3642217

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 23 Apr 2021 20:51:21 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 22 Apr 2021 18:07:10 |



US3642217

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:16:22

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 23 Apr 2021 20:51:21 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 22 Apr 2021 18:07:10 |

US3642217

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:16:22

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 23 Apr 2021 20:51:21 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Apr 2021 18:07:10 |

US3642217

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:16:22

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard unlocked.       | (b) (4), (b) (6)            | 03 May 2021 19:16:41 |
| Data hard locked.         |                             | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:50 |
| Data hard locked.         |                             | 01 May 2021 20:11:07 |
| Data hard unlocked.       |                             | 30 Apr 2021 08:38:49 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 23 Apr 2021 20:51:21 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 22 Apr 2021 18:07:10 |

US3642217

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:16:22

[Start Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 22 Apr 2021 18:07:10 |

US3642217

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:16:22

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 22 Apr 2021 18:07:10 |

US3642217

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:16:22

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 22 Apr 2021 18:07:10 |

US3642217

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:16:22

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard unlocked. | (b) (4), (b) (6) | 03 May 2021 19:16:41 |
| Data hard locked.   |                  | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:50 |
| Data hard locked.   |                  | 01 May 2021 20:11:07 |
| Data hard unlocked. |                  | 30 Apr 2021 08:38:49 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered empty. | System           | 22 Apr 2021 18:07:10 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:55 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:05:59 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:32:42 |



US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                             | 02 May 2021 07:09:55 |
| Data hard locked.          |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:05:59 |
| User entered '15 Sep 2020' | Son Do (b) (4)              | 17 Sep 2020 16:32:42 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:55 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:05:59 |
| User entered '14:08'      | Son Do (b) (4)              | 17 Sep 2020 16:32:42 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked.              |                  | 02 May 2021 07:09:55 |
| Data hard locked.                |                  | 28 Apr 2021 19:15:41 |
| User entered '15 Sep 2020 14:08' | System           | 17 Sep 2020 16:32:42 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[Height \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:55 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:05:59 |
| User entered '155' cm     | Son Do (b) (4)              | 17 Sep 2020 16:32:42 |
| DataPoint set to visible. | System                      | 15 Sep 2020 22:41:16 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[Weight \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:55 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:05:59 |
| User entered '67.2' kg    | Son Do (b) (4)              | 17 Sep 2020 16:32:42 |
| DataPoint set to visible. | System                      | 15 Sep 2020 22:41:16 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                  | 02 May 2021 07:09:55 |
| Data hard locked.         |                  | 28 Apr 2021 19:15:41 |
| User entered '27.97086'   |                  | 17 Sep 2020 16:32:42 |
| DataPoint set to visible. | System           | 15 Sep 2020 22:41:16 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                  | 02 May 2021 07:09:55 |
| Data hard locked.         |                  | 28 Apr 2021 19:15:41 |
| User entered 'kg/m2'      | System           | 17 Sep 2020 16:32:42 |
| DataPoint set to visible. | System           | 15 Sep 2020 22:41:16 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

Temperature (xxx.x)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 02 May 2021 22:51:58 |
| Data hard unlocked.  | (b) (4), (b) (6)        | 02 May 2021 07:09:55 |
| Data hard locked.  | (b) (4), (b) (6)        | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:59 |
| DataPoint Verified.  | (b) (4), (b) (6)        | 08 Dec 2020 18:05:59 |
| User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).             | (b) (4)                 | 16 Oct 2020 12:52:41 |
| Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'revised' (Site from DM). | Megan Loughran (b) (4)  | 15 Oct 2020 04:33:11 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution  | (b) (4)                 | 15 Oct 2020 04:33:07 |
| User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, 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 Sep 2020 23:40:31 |
| User entered '98.2' F  | Son Do (b) (4)          | 17 Sep 2020 16:32:42 |



US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[Route of measurement](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                                   | 02 May 2021 07:09:55 |
| Data hard locked.  |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.                                  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:59 |
| User entered empty; reason for change Per Query Resolution | Megan Loughran (b) (4)<br>(b) (4) | 15 Oct 2020 04:33:07 |
| User entered 'Axillary (Axillary)'                         | Son Do (b) (4)                    | 17 Sep 2020 16:32:42 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:55 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:05:59 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:32:42 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[Pulse \(xxx\)](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.   |                                   | 02 May 2021 07:09:55 |
| Data hard locked.   |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.   | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:59 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Megan Loughran (b) (4)<br>(b) (4) | 15 Oct 2020 04:33:07 |
| User entered '80'   | Son Do (b) (4)                    | 17 Sep 2020 16:32:42 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:55 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered 'bpm'  | System           | 17 Sep 2020 16:32:42 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[Respiratory Rate \(xxx\)](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.   |                                   | 02 May 2021 07:09:55 |
| Data hard locked.   |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.   | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:59 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Megan Loughran (b) (4)<br>(b) (4) | 15 Oct 2020 04:33:07 |
| User entered '16'   | Son Do (b) (4)                    | 17 Sep 2020 16:32:42 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                  | 02 May 2021 07:09:55 |
| Data hard locked.          |                  | 28 Apr 2021 19:15:41 |
| User entered 'breaths/min' | System           | 17 Sep 2020 16:32:42 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

Systolic Blood Pressure (xxx)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.   |                                   | 02 May 2021 07:09:55 |
| Data hard locked.   |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.   | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:59 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Megan Loughran (b) (4)<br>(b) (4) | 15 Oct 2020 04:33:07 |
| User entered '147'  | Son Do (b) (4)                    | 17 Sep 2020 16:32:42 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:55 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered 'mmHg' | System           | 17 Sep 2020 16:32:42 |



US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

Diastolic Blood Pressure (xxx)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 02 May 2021 22:51:58 |
| Data hard unlocked.   |                                   | 02 May 2021 07:09:55 |
| Data hard locked.   |                                   | 28 Apr 2021 19:15:41 |
| User signature succeeded.   | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:05:59 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Megan Loughran (b) (4)<br>(b) (4) | 15 Oct 2020 04:33:07 |
| User entered '77'   | Son Do (b) (4)                    | 17 Sep 2020 16:32:42 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:55 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |
| User entered 'mmHg' | System           | 17 Sep 2020 16:32:42 |

**US3642217**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Height \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:55 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |

US3642217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

Weight (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:58 |
| Data hard unlocked. |                  | 02 May 2021 07:09:55 |
| Data hard locked.   |                  | 28 Apr 2021 19:15:41 |

US3642217

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:16:22

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:58 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:06:29 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:31:59 |

US3642217

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:16:22

Date of examination (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                             | 02 May 2021 07:09:58 |
| Data hard locked.          |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:06:29 |
| User entered '15 Sep 2020' | Son Do (b) (4)              | 17 Sep 2020 16:31:59 |

US3642217

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:16:22

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.        |                             | 02 May 2021 07:09:16 |
| Data hard locked.          |                             | 28 Apr 2021 19:15:39 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:06:42 |
| User entered '15 Sep 2020' | Son Do (b) (4)              | 17 Sep 2020 16:34:23 |

US3642217

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:16:22

[Is the participant of childbearing potential?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:16 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:39 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:06:42 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:23 |



US3642217

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:16:22

[If No, what is the reason?](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 02 May 2021 22:51:58 |
| Data hard unlocked.  |                         | 02 May 2021 07:09:16 |
| Data hard locked.  |                         | 28 Apr 2021 19:15:39 |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4), (b) (6)        | 08 Dec 2020 18:06:42 |
| User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).           |                         | 16 Oct 2020 16:37:03 |
| Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'added' (Site from DM). | Megan Loughran (b) (4)  | 15 Oct 2020 04:33:19 |
| User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).           | (b) (4), (b) (6)        | 07 Oct 2020 06:06:40 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)'   | Son Do (b) (4)          | 17 Sep 2020 16:34:23 |

US3642217

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:16:22

If Partner medically sterile or Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:16 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:39 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:06:42 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:34:23 |

US3642217

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:16:22

If Surgically sterile, date of surgery (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:16 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:39 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:06:42 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:34:23 |

US3642217

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:16:22

Date of surgery unknown

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:16 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:39 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:06:42 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:34:23 |

US3642217

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:16:22

If Post-menopausal, date of last menstruation (dd MMM yyyy)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.                           |                             | 02 May 2021 07:09:16 |
| Data hard locked.                             |                             | 28 Apr 2021 19:15:39 |
| User signature succeeded.                     | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                           | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:06:42 |
| User entered 'UN UNK 1985' reason for change: | Megan Loughran (b) (4)      | 24 Nov 2020 22:36:53 |
| Data Entry Error                              | (b) (4)                     |                      |
| User entered empty.                           | Son Do (b) (4)              | 17 Sep 2020 16:34:23 |

US3642217

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:16:22

Date of last menstruation unknown

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.                                  |                             | 02 May 2021 07:09:16 |
| Data hard locked.                                    |                             | 28 Apr 2021 19:15:39 |
| User signature succeeded.                            | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                                  | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:06:42 |
| User entered '0' reason for change: Data Entry Error | Megan Loughran (b) (4)      | 24 Nov 2020 22:36:53 |
| User entered '1'                                     | (b) (4)<br>Son Do (b) (4)   | 17 Sep 2020 16:34:23 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |



US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

**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)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

**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)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

[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)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

**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)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

**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)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

[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)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

**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)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |



US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

**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)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

[Other](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

[Specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

No Risk Identified

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                           | 02 May 2021 07:09:22 |
| Data hard locked.         |                           | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:59 |
| User entered '0'          | (b) (4)<br>Son Do (b) (4) | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

Resides in Nursing Home or Assisted Living Facility

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

**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)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

**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)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

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)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |



US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

[Resides in a single family home](#) (i.e., detached housing)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered 'I'          | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

[Other](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                           | 02 May 2021 07:09:22 |
| Data hard locked.         |                           | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:59 |
| User entered '0'          | (b) (4)<br>Son Do (b) (4) | 17 Sep 2020 16:34:52 |

US3642217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:16:22

[Specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 22:51:58 |
| Data hard unlocked.       |                             | 02 May 2021 07:09:22 |
| Data hard locked.         |                             | 28 Apr 2021 19:15:41 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:07:10 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:34:52 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Was this visit performed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:07:18 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:41:28 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:07:18 |
| User entered '15 Sep 2020' | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:41:28 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded.      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:07:18 |
| User entered 'Clinic (Clinic)' | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:41:28 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'VISIT1' | System           | 15 Sep 2020 22:41:28 |

US3642217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:16:22

What was the date of randomization? (dd MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)          | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 08 Dec 2020 19:23:46 |
| User entered '15 SEP 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 15 Sep 2020 22:14:07 |



US3642217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:16:22

[What was the participant's randomization number?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)          | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 08 Dec 2020 19:23:48 |
| User entered '191017'     | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 15 Sep 2020 22:14:07 |

US3642217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:16:22

[In what Cohort was the participant enrolled?](#)

| Audit                         | User                             | Time (GMT)           |
|-------------------------------|----------------------------------|----------------------|
| Data hard locked.             | (b) (4), (b) (6)                 | 27 Mar 2021 09:39:53 |
| User signature succeeded.     | Stephen Spector (b) (4)          | 13 Feb 2021 17:54:59 |
| DataPoint Verified.           | (b) (4)<br>(b) (4), (b) (6)      | 08 Dec 2020 19:23:50 |
| User entered '>=65 years (3)' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 15 Sep 2020 22:14:07 |

US3642217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:16:22

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)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:24:02 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:43:53 |

US3642217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:16:22

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)        | 27 Mar 2021 09:39:53 |
| User closed query 'Please check and confirm if cardiac disease should be checked 'yes'. Per source there is no indication of significant cardiac disease. ' (Site from CRA).             | (b) (4), (b) (6)        | 18 Feb 2021 23:56:50 |
| DataPoint Verified.  | (b) (4), (b) (6)        | 18 Feb 2021 23:56:47 |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:59 |
| User entered 'Yes (Y)' reason for change: Data Entry Error   | (b) (4)                 |                      |
| Query 'Please check and confirm if cardiac disease should be checked 'yes'. Per source there is no indication of significant cardiac disease. ' answered with 'revised' (Site from CRA). | Megan Loughran (b) (4)  | 14 Dec 2020 19:09:23 |
|  | (b) (4)                 |                      |
| Query 'Please check and confirm if cardiac disease should be checked 'yes'. Per source there is no indication of significant cardiac disease. ' answered with 'revised' (Site from CRA). | Megan Loughran (b) (4)  | 14 Dec 2020 19:06:33 |
|  | (b) (4)                 |                      |
| User entered 'No (N)' reason for change: Data Entry Error  | Megan Loughran (b) (4)  | 14 Dec 2020 19:06:28 |
|  | (b) (4)                 |                      |
| User opened query 'Please check and confirm if cardiac disease should be checked 'yes'. Per source there is no indication of significant cardiac disease. ' (Site from CRA).             | (b) (4), (b) (6)        | 08 Dec 2020 19:25:10 |
|  |                         |                      |
| User entered 'Yes (Y)'   | Megan Loughran (b) (4)  | 15 Sep 2020 22:43:53 |
|  | (b) (4)                 |                      |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:16:22**

Severe obesity (body mass index > or = 40kg/m2)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:24:05 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:43:53 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:16:22**

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:24:09 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:43:53 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:16:22**

[Liver Disease](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:24:11 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 15 Sep 2020 22:43:53 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:16:22**

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.                    | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:24:24 |
| User entered 'No (N)'                        | Megan Loughran (b) (4)      | 15 Oct 2020 04:34:21 |
| Amendment Manager: DataPoint set to visible. | (b) (4)                     |                      |
| Amendment Manager inserted this DataPoint.   | System                      | 19 Sep 2020 09:18:30 |
|  | System                      | 19 Sep 2020 09:18:29 |



US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:16:22

Height

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:59 |
| DataPoint Verified.  | (b) (4), (b) (6)        | 08 Dec 2020 18:19:42 |
| User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).             |                         | 16 Oct 2020 18:08:53 |
| Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'revised' (Site from DM). | Megan Loughran (b) (4)  | 15 Oct 2020 04:34:37 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution  | Megan Loughran (b) (4)  | 15 Oct 2020 04:34:32 |
| User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).             | (b) (4), (b) (6)        | 24 Sep 2020 23:40:21 |
| User entered '155' cm  | Son Do (b) (4)          | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:16:22

Weight

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:43 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Megan Loughran (b) (4)      | 15 Oct 2020 04:34:32 |
| User entered '67.2' kg  | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:16:22

Height

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:42 |
| User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).             |                             | 16 Oct 2020 18:08:53 |
| Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'revised' (Site from DM). | Megan Loughran (b) (4)      | 15 Oct 2020 04:34:37 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution  | (b) (4)                     | 15 Oct 2020 04:34:32 |
| User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).             | (b) (4), (b) (6)            | 24 Sep 2020 23:40:21 |
| User entered '155' cm  | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:16:22

Weight

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:43 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Megan Loughran (b) (4)      | 15 Oct 2020 04:34:32 |
| User entered '67.2' kg  | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Son Do (b) (4)   | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:18:23 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:18:25 |
| User entered '15 Sep 2020' | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:18:27 |
| User entered '14:08'      | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |



US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered '15 Sep 2020 14:08' | System           | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:18:28 |
| User entered '98.2' F     | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Route of measurement](#)

| Audit  | User                    | Time (GMT)                                   |
|--|-------------------------|--|
| Data hard locked.  | (b) (4), (b) (6)        | 27 Mar 2021 09:39:53                         |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:59                         |
| User closed query 'Per source axillary is not indicated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified. | (b) (4), (b) (6)        | 21 Jan 2021 22:43:07<br>21 Jan 2021 22:43:05 |
| Query 'Per source axillary is not indicated. Please reconcile. ' answered with 'revised' (Site from CRA).            | Megan Loughran (b) (4)  | 14 Dec 2020 19:10:58                         |
| User entered 'Oral (Oral)' reason for change: Data Entry Error   | Megan Loughran (b) (4)  | 14 Dec 2020 19:10:54                         |
| User opened query 'Per source axillary is not indicated. Please reconcile. ' (Site from CRA).                        | (b) (4), (b) (6)        | 08 Dec 2020 18:18:51                         |
| User entered 'Axillary (Axillary)'   | Son Do (b) (4)          | 17 Sep 2020 16:33:33                         |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 22:43:08 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:18:31 |
| User entered '80'         | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'bpm' | System           | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:18:33 |
| User entered '16'         | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'breaths/min' | System           | 17 Sep 2020 16:33:33 |



US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:18:35 |
| User entered '147'        | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'mmHg' | System           | 17 Sep 2020 16:33:33 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:18:37 |
| User entered '77'         | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'mmHg' | System           | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:16:22

Height

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:42 |
| User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).             |                             | 16 Oct 2020 18:08:53 |
| Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'revised' (Site from DM). | Megan Loughran (b) (4)      | 15 Oct 2020 04:34:37 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution  | Megan Loughran (b) (4)      | 15 Oct 2020 04:34:32 |
| User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).             | (b) (4), (b) (6)            | 24 Sep 2020 23:40:21 |
| User entered '155' cm  | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:16:22

[Weight](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:43 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Megan Loughran (b) (4)      | 15 Oct 2020 04:34:32 |
| User entered '67.2' kg  | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Son Do (b) (4)   | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:18 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |



**US3642217**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:19 |
| User entered '15 Sep 2020' | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:21 |
| User entered '16:29'      | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered '15 Sep 2020 16:29' | System           | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:22 |
| User entered '97.9' F     | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Route of measurement](#)

| Audit  | User                    | Time (GMT)                                   |
|--|-------------------------|--|
| Data hard locked.  | (b) (4), (b) (6)        | 27 Mar 2021 09:39:53                         |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:59                         |
| User closed query 'Per source axillary is not indicated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified. | (b) (4), (b) (6)        | 21 Jan 2021 22:43:17<br>21 Jan 2021 22:43:16 |
| Query 'Per source axillary is not indicated. Please reconcile. ' answered with 'revised' (Site from CRA).            | Megan Loughran (b) (4)  | 14 Dec 2020 19:11:07                         |
| User entered 'Oral (Oral)' reason for change: Data Entry Error   | Megan Loughran (b) (4)  | 14 Dec 2020 19:11:04                         |
| User opened query 'Per source axillary is not indicated. Please reconcile. ' (Site from CRA).                        | (b) (4), (b) (6)        | 08 Dec 2020 18:19:38                         |
| User entered 'Axillary (Axillary)'   | Son Do (b) (4)          | 17 Sep 2020 16:33:33                         |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 22:43:18 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:24 |
| User entered '73'         | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'bpm' | System           | 17 Sep 2020 16:33:33 |



US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:26 |
| User entered '16'         | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'breaths/min' | System           | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:27 |
| User entered '128'        | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'mmHg' | System           | 17 Sep 2020 16:33:33 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:29 |
| User entered '65'         | Son Do (b) (4)              | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'mmHg' | System           | 17 Sep 2020 16:33:33 |

US3642217

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:16:22

[Was the physical examination performed?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.                                 | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.                                       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:50 |
| User entered 'No (N)' reason for change: Data Entry Error | Megan Loughran (b) (4)      | 24 Nov 2020 22:38:48 |
| User entered 'Yes (Y)'                                    | Son Do (b) (4)              | 17 Sep 2020 16:32:07 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:16:22**

**Date of examination (dd MMM yyyy)**

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.                              | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.                                    | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:19:50 |
| User entered empty; reason for change Data Entry Error | Megan Loughran (b) (4)      | 24 Nov 2020 22:38:48 |
| User entered '15 Sep 2020'                             | Son Do (b) (4)              | 17 Sep 2020 16:32:07 |



US3642217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

[Was study treatment given?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 08 Dec 2020 18:19:59 |
| User entered 'Yes (Y)'    |                         | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:16:22**

[If No, reason not given](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 08 Dec 2020 18:19:59 |
| User entered empty.       |                         | 15 Sep 2020 23:01:12 |

US3642217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

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)        | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 08 Dec 2020 18:19:59 |
| User entered empty.       |                         | 15 Sep 2020 23:01:12 |

US3642217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4), (b) (6)        | 08 Dec 2020 18:19:59 |
| User entered '15 Sep 2020' |                         | 15 Sep 2020 23:01:12 |

US3642217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 08 Dec 2020 18:19:59 |
| User entered '15:53'      |                         | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:16:22**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered '15 Sep 2020 15:53' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

[Which arm was used to give treatment?](#)

| Audit                                | User                    | Time (GMT)           |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)        | 27 Mar 2021 09:39:53 |
| User signature succeeded.            | Stephen Spector (b) (4) | 13 Feb 2021 17:54:59 |
| DataPoint Verified.                  | (b) (4), (b) (6)        | 08 Dec 2020 18:19:59 |
| User entered 'Right Arm (RIGHT ARM)' |                         | 15 Sep 2020 23:01:12 |



US3642217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| DataPoint Verified. |                  | 08 Dec 2020 18:19:59 |
| User entered 'ONCE' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'INTRAMUSCULAR' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:20:05 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:33:51 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:20:05 |
| User entered '15 Sep 2020' | Son Do (b) (4)              | 17 Sep 2020 16:33:51 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:20:05 |
| User entered '15:17'      | Son Do (b) (4)              | 17 Sep 2020 16:33:51 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered '15 Sep 2020 15:17' | System           | 17 Sep 2020 16:33:51 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:16:22**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:20:10 |
| User entered '15 Sep 2020' | Son Do (b) (4)              | 17 Sep 2020 16:34:03 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Son Do (b) (4)   | 17 Sep 2020 16:34:03 |



**US3642217**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:20:10 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:34:03 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:20:10 |
| User entered '15:24'      | Son Do (b) (4)              | 17 Sep 2020 16:34:03 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered '15 Sep 2020 15:24' | System           | 17 Sep 2020 16:34:03 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Lab Test](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)' | (b) (4)          | 17 Sep 2020 16:34:03 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:20:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:34:03 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:16:22**

**Collection time (00:00 - 23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:20:10 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:34:03 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered empty. | System           | 17 Sep 2020 16:34:03 |

**US3642217**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:20:17 |
| User entered 'Yes (Y)'    | Nancy Tang (b) (4)          | 23 Sep 2020 18:35:21 |



**US3642217**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'I'  | System           | 23 Sep 2020 18:35:21 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:26:51', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '171c3534-944b-4083-bbda-fb5d4fb9b560' | System           | 15 Sep 2020 23:27:30 |
| User entered 'Yes (Y)'   | System           | 15 Sep 2020 23:27:30 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:27:11', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '171c3534-944b-4083-bbda-fb5d4fb9b560' | System           | 15 Sep 2020 23:27:30 |
| User entered '97.8'  | System           | 15 Sep 2020 23:27:30 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:27:17', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '171c3534-944b-4083-bbda-fb5d4fb9b560' | System           | 15 Sep 2020 23:27:30 |
| User entered 'No (N)'  | System           | 15 Sep 2020 23:27:30 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:27:26', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '171c3534-944b-4083-bbda-fb5d4fb9b560' | System           | 15 Sep 2020 23:27:30 |
| User entered '15 Sep 2020 16:27'   | System           | 15 Sep 2020 23:27:30 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Sep 2020 16:13' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Sep 2020 18:43' | System           | 15 Sep 2020 23:01:12 |



US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.                                | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 1, after vaccination (at home)' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

To **TREAT** pain or fever that has already occurred

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Sep 2020 19:38' | System           | 15 Sep 2020 23:01:12 |



**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '16 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 2' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:46:21', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c79d40fa-d8b6-40e5-80e5-001fe3c3e363' | System           | 17 Sep 2020 01:47:00 |
| User entered 'Yes (Y)'   | System           | 17 Sep 2020 01:47:00 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:46:32', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c79d40fa-d8b6-40e5-80e5-001fe3c3e363' | System           | 17 Sep 2020 01:47:00 |
| User entered '97.8'  | System           | 17 Sep 2020 01:47:00 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:46:42', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c79d40fa-d8b6-40e5-80e5-001fe3c3e363' | System           | 17 Sep 2020 01:47:00 |
| User entered 'No (N)'  | System           | 17 Sep 2020 01:47:00 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:46:56', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c79d40fa-d8b6-40e5-80e5-001fe3c3e363' | System           | 17 Sep 2020 01:47:00 |
| User entered '16 Sep 2020 18:46'   | System           | 17 Sep 2020 01:47:00 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '16 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:16:22

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '17 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |



US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 3' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:42:25', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '734a983a-a150-43c9-81a9-afd15c566134' | System           | 18 Sep 2020 05:43:10 |
| User entered 'Yes (Y)'   | System           | 18 Sep 2020 05:43:10 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:42:46', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '734a983a-a150-43c9-81a9-afd15c566134' | System           | 18 Sep 2020 05:43:10 |
| User entered '97.6'  | System           | 18 Sep 2020 05:43:10 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:42:58', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '734a983a-a150-43c9-81a9-afd15c566134' | System           | 18 Sep 2020 05:43:10 |
| User entered 'No (N)'  | System           | 18 Sep 2020 05:43:10 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:43:06', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '734a983a-a150-43c9-81a9-afd15c566134' | System           | 18 Sep 2020 05:43:10 |
| User entered '17 Sep 2020 22:43'   | System           | 18 Sep 2020 05:43:10 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '17 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '18 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 4' | System           | 15 Sep 2020 23:01:12 |



US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:14:40', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0eba849d-eebf-4a0c-ae52-a343a9cbd4d6' | System           | 19 Sep 2020 04:15:01 |
| User entered 'Yes (Y)'   | System           | 19 Sep 2020 04:15:01 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:14:48', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0eba849d-eebf-4a0c-ae52-a343a9cbd4d6' | System           | 19 Sep 2020 04:15:01 |
| User entered '98.4'  | System           | 19 Sep 2020 04:15:01 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:14:51', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0eba849d-eebf-4a0c-ae52-a343a9cbd4d6' | System           | 19 Sep 2020 04:15:01 |
| User entered 'No (N)'  | System           | 19 Sep 2020 04:15:01 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:14:58', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0eba849d-eebf-4a0c-ae52-a343a9cbd4d6' | System           | 19 Sep 2020 04:15:01 |
| User entered '18 Sep 2020 21:14'   | System           | 19 Sep 2020 04:15:01 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '18 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '19 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 5' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T20:58:07', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '81e8a288-0c08-4297-ac87-05e33bb2db22' | System           | 20 Sep 2020 04:00:19 |
| User entered 'Yes (Y)'   | System           | 20 Sep 2020 04:00:19 |



US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T20:59:48', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '81e8a288-0c08-4297-ac87-05e33bb2db22' | System           | 20 Sep 2020 04:00:19 |
| User entered '97.8'  | System           | 20 Sep 2020 04:00:19 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T20:58:57', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '81e8a288-0c08-4297-ac87-05e33bb2db22' | System           | 20 Sep 2020 04:00:19 |
| User entered 'Yes (Y)'   | System           | 20 Sep 2020 04:00:19 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:16:22

To **TREAT** pain or fever that has already occurred

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 25 Feb 2021 13:09:40 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PARTICIPANT WAS CONTACTED BY STUDY STAFF - SEE SAFETY CALL SOURCE DOC FOR ADDITIONAL INFORMATION.' (Site from System). | Colleen McLellan (b) (4) | 19 Nov 2020 06:02:50 |
| 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 Sep 2020 04:00:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T20:59:39', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '81e8a288-0c08-4297-ac87-05e33bb2db22'  | System                   | 20 Sep 2020 04:00:19 |
| User entered '1'  | System                   | 20 Sep 2020 04:00:19 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:16:22

To **PREVENT** pain or fever from occurring

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T20:59:39', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '81e8a288-0c08-4297-ac87-05e33bb2db22' | System           | 20 Sep 2020 04:00:19 |
| User entered '0'   | System           | 20 Sep 2020 04:00:19 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:00:12', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '81e8a288-0c08-4297-ac87-05e33bb2db22' | System           | 20 Sep 2020 04:00:19 |
| User entered '19 Sep 2020 21:00'   | System           | 20 Sep 2020 04:00:19 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '19 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '20 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 6' | System           | 15 Sep 2020 23:01:12 |



US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:36:57', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '199d6384-7c9f-435d-989e-5ecfc332b2e2' | System           | 21 Sep 2020 01:37:22 |
| User entered 'Yes (Y)'   | System           | 21 Sep 2020 01:37:22 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:37:04', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '199d6384-7c9f-435d-989e-5ecfc332b2e2' | System           | 21 Sep 2020 01:37:22 |
| User entered '97.5'  | System           | 21 Sep 2020 01:37:22 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:37:08', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '199d6384-7c9f-435d-989e-5ecfc332b2e2' | System           | 21 Sep 2020 01:37:22 |
| User entered 'No (N)'  | System           | 21 Sep 2020 01:37:22 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:37:18', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '199d6384-7c9f-435d-989e-5ecfc332b2e2' | System           | 21 Sep 2020 01:37:22 |
| User entered '20 Sep 2020 18:37'   | System           | 21 Sep 2020 01:37:22 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '20 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '21 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 7' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |



US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

To **TREAT** pain or fever that has already occurred

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '21 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '22 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 15 Sep 2020 23:01:12 |



US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:27:52', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '587446f4-4767-4331-8a42-ad472a4a95d2' | System           | 15 Sep 2020 23:28:21 |
| User entered 'None (1)'  | System           | 15 Sep 2020 23:28:21 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Is there any **REDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:27:59', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '587446f4-4767-4331-8a42-ad472a4a95d2' | System           | 15 Sep 2020 23:28:21 |
| User entered 'No (N)'  | System           | 15 Sep 2020 23:28:21 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:28:04', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '587446f4-4767-4331-8a42-ad472a4a95d2' | System           | 15 Sep 2020 23:28:21 |
| User entered 'No (N)'  | System           | 15 Sep 2020 23:28:21 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:28:10', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '587446f4-4767-4331-8a42-ad472a4a95d2' | System           | 15 Sep 2020 23:28:21 |
| User entered 'None (1)'  | System           | 15 Sep 2020 23:28:21 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:28:18', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '587446f4-4767-4331-8a42-ad472a4a95d2' | System           | 15 Sep 2020 23:28:21 |
| User entered '15 Sep 2020 16:28'   | System           | 15 Sep 2020 23:28:21 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Sep 2020 16:13' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Sep 2020 18:43' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.                                | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 1, after vaccination (at home)' | System           | 15 Sep 2020 23:01:12 |



US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Sep 2020 19:38' | System           | 15 Sep 2020 23:01:12 |



**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '16 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 2' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:48:11', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '8233084b-f7a5-4314-8b69-58c28ca35032' | System           | 17 Sep 2020 01:48:51 |
| User entered 'None (1)'  | System           | 17 Sep 2020 01:48:51 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:48:15', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '8233084b-f7a5-4314-8b69-58c28ca35032' | System           | 17 Sep 2020 01:48:51 |
| User entered 'No (N)'  | System           | 17 Sep 2020 01:48:51 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:48:19', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '8233084b-f7a5-4314-8b69-58c28ca35032' | System           | 17 Sep 2020 01:48:51 |
| User entered 'No (N)'  | System           | 17 Sep 2020 01:48:51 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:48:37', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '8233084b-f7a5-4314-8b69-58c28ca35032' | System           | 17 Sep 2020 01:48:51 |
| User entered 'None (1)'  | System           | 17 Sep 2020 01:48:51 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:48:48', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '8233084b-f7a5-4314-8b69-58c28ca35032' | System           | 17 Sep 2020 01:48:51 |
| User entered '16 Sep 2020 18:48'   | System           | 17 Sep 2020 01:48:51 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '16 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |



**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '17 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 3' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:43:17', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b1596272-fd37-481f-a992-18abeaf59ce8' | System           | 18 Sep 2020 05:44:06 |
| User entered 'Does not interfere with activity (2)'  | System           | 18 Sep 2020 05:44:06 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:43:21', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b1596272-fd37-481f-a992-18abeaf59ce8' | System           | 18 Sep 2020 05:44:06 |
| User entered 'No (N)'  | System           | 18 Sep 2020 05:44:06 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:43:36', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b1596272-fd37-481f-a992-18abeaf59ce8' | System           | 18 Sep 2020 05:44:06 |
| User entered 'No (N)'  | System           | 18 Sep 2020 05:44:06 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:43:43', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b1596272-fd37-481f-a992-18abeaf59ce8' | System           | 18 Sep 2020 05:44:06 |
| User entered 'None (1)'  | System           | 18 Sep 2020 05:44:06 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:44:02', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b1596272-fd37-481f-a992-18abeaf59ce8' | System           | 18 Sep 2020 05:44:06 |
| User entered '17 Sep 2020 22:44'   | System           | 18 Sep 2020 05:44:06 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '17 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |



**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '18 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 4' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:15:06', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0bc60bea-d4a2-4552-bcdd-ffd5c8380db7' | System           | 20 Sep 2020 03:57:14 |
| User entered 'None (1)'  | System           | 20 Sep 2020 03:57:14 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Is there any **REDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:15:27', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0bc60bea-d4a2-4552-bcdd-ffd5c8380db7' | System           | 20 Sep 2020 03:57:14 |
| User entered 'No (N)'  | System           | 20 Sep 2020 03:57:14 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:15:30', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0bc60bea-d4a2-4552-bcdd-ffd5c8380db7' | System           | 20 Sep 2020 03:57:14 |
| User entered 'No (N)'  | System           | 20 Sep 2020 03:57:14 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:15:39', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0bc60bea-d4a2-4552-bcdd-ffd5c8380db7' | System           | 20 Sep 2020 03:57:14 |
| User entered 'None (1)'  | System           | 20 Sep 2020 03:57:14 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:15:54', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0bc60bea-d4a2-4552-bcdd-ffd5c8380db7' | System           | 20 Sep 2020 03:57:14 |
| User entered '18 Sep 2020 21:15'   | System           | 20 Sep 2020 03:57:14 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '18 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |



**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '19 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 5' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:00:18', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'd197b53a-6ed2-4a3a-a4fe-d0173412d396' | System           | 20 Sep 2020 04:00:43 |
| User entered 'None (1)'  | System           | 20 Sep 2020 04:00:43 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:00:23', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'd197b53a-6ed2-4a3a-a4fe-d0173412d396' | System           | 20 Sep 2020 04:00:43 |
| User entered 'No (N)'  | System           | 20 Sep 2020 04:00:43 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:00:26', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'd197b53a-6ed2-4a3a-a4fe-d0173412d396' | System           | 20 Sep 2020 04:00:43 |
| User entered 'No (N)'  | System           | 20 Sep 2020 04:00:43 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:00:32', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'd197b53a-6ed2-4a3a-a4fe-d0173412d396' | System           | 20 Sep 2020 04:00:43 |
| User entered 'None (1)'  | System           | 20 Sep 2020 04:00:43 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:00:37', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'd197b53a-6ed2-4a3a-a4fe-d0173412d396' | System           | 20 Sep 2020 04:00:43 |
| User entered '19 Sep 2020 21:00'   | System           | 20 Sep 2020 04:00:43 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '19 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |



**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '20 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 6' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:37:23', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'db63c041-bf73-4ece-bbcc-b55110f07dcb' | System           | 21 Sep 2020 01:38:25 |
| User entered 'None (1)'  | System           | 21 Sep 2020 01:38:25 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:37:40', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'db63c041-bf73-4ece-bbcc-b55110f07dcb' | System           | 21 Sep 2020 01:38:25 |
| User entered 'No (N)'  | System           | 21 Sep 2020 01:38:25 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:37:44', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'db63c041-bf73-4ece-bbcc-b55110f07dcb' | System           | 21 Sep 2020 01:38:25 |
| User entered 'No (N)'  | System           | 21 Sep 2020 01:38:25 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:37:56', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'db63c041-bf73-4ece-bbcc-b55110f07dcb' | System           | 21 Sep 2020 01:38:25 |
| User entered 'None (1)'  | System           | 21 Sep 2020 01:38:25 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:38:18', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'db63c041-bf73-4ece-bbcc-b55110f07dcb' | System           | 21 Sep 2020 01:38:25 |
| User entered '20 Sep 2020 18:38'   | System           | 21 Sep 2020 01:38:25 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '20 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |



**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '21 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 7' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |



**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '21 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '22 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:33:32', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0427625c-c71e-4885-9615-c15a9acdd26f' User entered 'None (0)' | System           | 15 Sep 2020 23:34:12 |
|  | System           | 15 Sep 2020 23:34:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:33:41', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0427625c-c71e-4885-9615-c15a9acdd26f' User entered 'None (0)' | System           | 15 Sep 2020 23:34:12 |
|  | System           | 15 Sep 2020 23:34:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:33:46', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0427625c-c71e-4885-9615-c15a9acdd26f' User entered 'None (0)' | System           | 15 Sep 2020 23:34:12 |
|  | System           | 15 Sep 2020 23:34:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:33:50', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0427625c-c71e-4885-9615-c15a9acdd26f' User entered 'None (0)' | System           | 15 Sep 2020 23:34:12 |
|  | System           | 15 Sep 2020 23:34:12 |



US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:33:53', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0427625c-c71e-4885-9615-c15a9acdd26f' | System           | 15 Sep 2020 23:34:12 |
| User entered 'None (0)'  | System           | 15 Sep 2020 23:34:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:33:55', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0427625c-c71e-4885-9615-c15a9acdd26f' | System           | 15 Sep 2020 23:34:12 |
| User entered 'None (0)'  | System           | 15 Sep 2020 23:34:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:34:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0427625c-c71e-4885-9615-c15a9acdd26f' | System           | 15 Sep 2020 23:34:12 |
| User entered 'No (N)'  | System           | 15 Sep 2020 23:34:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-15T16:34:06', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0427625c-c71e-4885-9615-c15a9acdd26f' User entered '15 Sep 2020 16:34' | System           | 15 Sep 2020 23:34:12 |
|   | System           | 15 Sep 2020 23:34:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Sep 2020 16:13' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Sep 2020 18:43' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.                                | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 1, after vaccination (at home)' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |



US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Sep 2020 19:38' | System           | 15 Sep 2020 23:01:12 |



**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '16 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 2' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:48:57', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fdd6eb30-9d3e-4f59-923f-eff0cc068434' | System           | 17 Sep 2020 01:49:42 |
| User entered 'None (0)'  | System           | 17 Sep 2020 01:49:42 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:49:01', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fdd6eb30-9d3e-4f59-923f-eff0cc068434' | System           | 17 Sep 2020 01:49:42 |
| User entered 'None (0)'  | System           | 17 Sep 2020 01:49:42 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:49:05', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fdd6eb30-9d3e-4f59-923f-eff0cc068434' | System           | 17 Sep 2020 01:49:42 |
| User entered 'None (0)'  | System           | 17 Sep 2020 01:49:42 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:49:13', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fdd6eb30-9d3e-4f59-923f-eff0cc068434' | System           | 17 Sep 2020 01:49:42 |
| User entered 'None (0)'  | System           | 17 Sep 2020 01:49:42 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:49:16', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fdd6eb30-9d3e-4f59-923f-eff0cc068434' | System           | 17 Sep 2020 01:49:42 |
| User entered 'None (0)'  | System           | 17 Sep 2020 01:49:42 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:49:19', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fdd6eb30-9d3e-4f59-923f-eff0cc068434' | System           | 17 Sep 2020 01:49:42 |
| User entered 'None (0)'  | System           | 17 Sep 2020 01:49:42 |



US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:49:26', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fdd6eb30-9d3e-4f59-923f-eff0cc068434' | System           | 17 Sep 2020 01:49:42 |
| User entered 'No (N)'  | System           | 17 Sep 2020 01:49:42 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-16T18:49:38', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fdd6eb30-9d3e-4f59-923f-eff0cc068434' | System           | 17 Sep 2020 01:49:42 |
| User entered '16 Sep 2020 18:49'   | System           | 17 Sep 2020 01:49:42 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '16 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '17 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 3' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:44:10', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3a8d1168-acdf-4716-b439-34f4463b4b0b' | System           | 18 Sep 2020 05:45:31 |
| User entered 'None (0)'  | System           | 18 Sep 2020 05:45:31 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:44:32', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3a8d1168-acdf-4716-b439-34f4463b4b0b' | System           | 18 Sep 2020 05:45:31 |
| User entered 'None (0)'  | System           | 18 Sep 2020 05:45:31 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:44:36', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3a8d1168-acdf-4716-b439-34f4463b4b0b' | System           | 18 Sep 2020 05:45:31 |
| User entered 'None (0)'  | System           | 18 Sep 2020 05:45:31 |



US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:44:44', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3a8d1168-acdf-4716-b439-34f4463b4b0b' | System           | 18 Sep 2020 05:45:31 |
| User entered 'None (0)'  | System           | 18 Sep 2020 05:45:31 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:45:02', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3a8d1168-acdf-4716-b439-34f4463b4b0b' | System           | 18 Sep 2020 05:45:31 |
| User entered 'None (0)'  | System           | 18 Sep 2020 05:45:31 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:45:06', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3a8d1168-acdf-4716-b439-34f4463b4b0b' | System           | 18 Sep 2020 05:45:31 |
| User entered 'None (0)'  | System           | 18 Sep 2020 05:45:31 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:45:10', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3a8d1168-acdf-4716-b439-34f4463b4b0b' | System           | 18 Sep 2020 05:45:31 |
| User entered 'No (N)'  | System           | 18 Sep 2020 05:45:31 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-17T22:45:28', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3a8d1168-acdf-4716-b439-34f4463b4b0b' | System           | 18 Sep 2020 05:45:31 |
| User entered '17 Sep 2020 22:45'   | System           | 18 Sep 2020 05:45:31 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '17 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '18 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 4' | System           | 15 Sep 2020 23:01:12 |



US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:16:04', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e182e8b0-f775-482e-8a17-c6b7c679e3ec' | System           | 20 Sep 2020 03:57:14 |
| User entered 'None (0)'  | System           | 20 Sep 2020 03:57:14 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:16:09', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e182e8b0-f775-482e-8a17-c6b7c679e3ec' | System           | 20 Sep 2020 03:57:14 |
| User entered 'None (0)'  | System           | 20 Sep 2020 03:57:14 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:16:21', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e182e8b0-f775-482e-8a17-c6b7c679e3ec' | System           | 20 Sep 2020 03:57:14 |
| User entered 'None (0)'  | System           | 20 Sep 2020 03:57:14 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:16:25', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e182e8b0-f775-482e-8a17-c6b7c679e3ec' | System           | 20 Sep 2020 03:57:14 |
| User entered 'None (0)'  | System           | 20 Sep 2020 03:57:14 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:16:29', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e182e8b0-f775-482e-8a17-c6b7c679e3ec' | System           | 20 Sep 2020 03:57:14 |
| User entered 'None (0)'  | System           | 20 Sep 2020 03:57:14 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:16:32', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e182e8b0-f775-482e-8a17-c6b7c679e3ec' | System           | 20 Sep 2020 03:57:14 |
| User entered 'None (0)'  | System           | 20 Sep 2020 03:57:14 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:16:37', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e182e8b0-f775-482e-8a17-c6b7c679e3ec' | System           | 20 Sep 2020 03:57:14 |
| User entered 'No (N)'  | System           | 20 Sep 2020 03:57:14 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-18T21:16:46', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e182e8b0-f775-482e-8a17-c6b7c679e3ec' | System           | 20 Sep 2020 03:57:14 |
| User entered '18 Sep 2020 21:16'   | System           | 20 Sep 2020 03:57:14 |



**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '18 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '19 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 5' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:00:52', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0f6bb86e-4556-4ee0-95e9-360d312fa35c' | System           | 20 Sep 2020 04:01:51 |
| User entered 'None (0)'  | System           | 20 Sep 2020 04:01:51 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:01:01', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0f6bb86e-4556-4ee0-95e9-360d312fa35c' | System           | 20 Sep 2020 04:01:51 |
| User entered 'None (0)'  | System           | 20 Sep 2020 04:01:51 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:01:10', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0f6bb86e-4556-4ee0-95e9-360d312fa35c' | System           | 20 Sep 2020 04:01:51 |
| User entered 'None (0)'  | System           | 20 Sep 2020 04:01:51 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:01:29', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0f6bb86e-4556-4ee0-95e9-360d312fa35c' | System           | 20 Sep 2020 04:01:51 |
| User entered 'None (0)'  | System           | 20 Sep 2020 04:01:51 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:01:34', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0f6bb86e-4556-4ee0-95e9-360d312fa35c' | System           | 20 Sep 2020 04:01:51 |
| User entered 'None (0)'  | System           | 20 Sep 2020 04:01:51 |



US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:01:37', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0f6bb86e-4556-4ee0-95e9-360d312fa35c' | System           | 20 Sep 2020 04:01:51 |
| User entered 'None (0)'  | System           | 20 Sep 2020 04:01:51 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:01:40', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0f6bb86e-4556-4ee0-95e9-360d312fa35c' | System           | 20 Sep 2020 04:01:51 |
| User entered 'No (N)'  | System           | 20 Sep 2020 04:01:51 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-19T21:01:45', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '0f6bb86e-4556-4ee0-95e9-360d312fa35c' | System           | 20 Sep 2020 04:01:51 |
| User entered '19 Sep 2020 21:01'   | System           | 20 Sep 2020 04:01:51 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '19 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '20 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 6' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:38:23', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3abb02ab-f751-4273-8c62-63f3dfb16b14' | System           | 21 Sep 2020 01:38:51 |
| User entered 'None (0)'  | System           | 21 Sep 2020 01:38:51 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:38:26', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3abb02ab-f751-4273-8c62-63f3dfb16b14' | System           | 21 Sep 2020 01:38:51 |
| User entered 'None (0)'  | System           | 21 Sep 2020 01:38:51 |



US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:38:28', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3abb02ab-f751-4273-8c62-63f3dfb16b14' | System           | 21 Sep 2020 01:38:51 |
| User entered 'None (0)'  | System           | 21 Sep 2020 01:38:51 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:38:31', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3abb02ab-f751-4273-8c62-63f3dfb16b14' | System           | 21 Sep 2020 01:38:51 |
| User entered 'None (0)'  | System           | 21 Sep 2020 01:38:51 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:38:34', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3abb02ab-f751-4273-8c62-63f3dfb16b14' | System           | 21 Sep 2020 01:38:51 |
| User entered 'None (0)'  | System           | 21 Sep 2020 01:38:51 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:38:36', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3abb02ab-f751-4273-8c62-63f3dfb16b14' | System           | 21 Sep 2020 01:38:51 |
| User entered 'None (0)'  | System           | 21 Sep 2020 01:38:51 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:38:40', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3abb02ab-f751-4273-8c62-63f3dfb16b14' | System           | 21 Sep 2020 01:38:51 |
| User entered 'No (N)'  | System           | 21 Sep 2020 01:38:51 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-09-20T18:38:47', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3abb02ab-f751-4273-8c62-63f3dfb16b14' | System           | 21 Sep 2020 01:38:51 |
| User entered '20 Sep 2020 18:38'   | System           | 21 Sep 2020 01:38:51 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '20 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '21 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |



US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 7' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |



**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '21 Sep 2020 12:00' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '22 Sep 2020 11:59' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:21:48 |
| User entered 'Yes (Y)'    | Nancy Tang (b) (4)          | 23 Sep 2020 18:42:02 |

**US3642217**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:21:48 |
| User entered '23 Sep 2020' | Nancy Tang (b) (4)          | 23 Sep 2020 18:42:02 |

**US3642217**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.                  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:21:48 |
| User entered 'Contact Made (CONTACT MADE)' | Nancy Tang (b) (4)          | 23 Sep 2020 18:42:02 |

US3642217

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:16:22

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:21:48 |
| User entered empty.       | Nancy Tang (b) (4)          | 23 Sep 2020 18:42:02 |

**US3642217**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:22:04 |
| User entered 'Yes (Y)'    | Nancy Tang (b) (4)          | 23 Sep 2020 18:42:08 |



**US3642217**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'I'  | System           | 23 Sep 2020 18:42:08 |

**US3642217**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Was Contact Attempted?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 18:23:22 |
| User entered 'Yes (Y)'    | Colleen McLellan (b) (4)<br>(b) (4) | 03 Oct 2020 18:02:05 |

US3642217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:16:22

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 27 Mar 2021 09:39:53 |
| User signature succeeded.   | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 08 Dec 2020 18:23:22 |
| User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).  |                          | 05 Oct 2020 05:12:30 |
| Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with '> 3 CONTACT ATTEMPTS MADE WITHIN TREATMENT WINDOW. SUBJECT RETURNED CALL TO STUDY STAFF AFTER TREATMENT WINDOW CLOSED. SEE SOURCE DOC FOR SPECIFIC DATES. ' (Site from System). | Colleen McLellan (b) (4) | 03 Oct 2020 18:02:52 |
| User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).  | System                   | 03 Oct 2020 18:02:05 |
| User entered '3 Oct 2020'   | Colleen McLellan (b) (4) | 03 Oct 2020 18:02:05 |

**US3642217**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded.                  | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                        | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 18:23:22 |
| User entered 'Contact Made (CONTACT MADE)' | Colleen McLellan (b) (4)<br>(b) (4) | 03 Oct 2020 18:02:05 |

US3642217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:16:22

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 18:23:22 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 03 Oct 2020 18:02:05 |

**US3642217**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 18:28:05 |
| User entered 'Yes (Y)'    | Colleen McLellan (b) (4)<br>(b) (4) | 03 Oct 2020 18:02:59 |

**US3642217**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'I'  | System           | 03 Oct 2020 18:02:59 |

**US3642217**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 08 Dec 2020 18:29:07 |
| User entered 'Yes (Y)'    |                         | 09 Oct 2020 00:02:10 |



**US3642217**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 08 Dec 2020 18:29:07 |
| User entered '8 Oct 2020' |                         | 09 Oct 2020 00:02:10 |

**US3642217**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)        | 27 Mar 2021 09:39:53 |
| User signature succeeded.                  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                        | (b) (4), (b) (6)        | 08 Dec 2020 18:29:07 |
| User entered 'Contact Made (CONTACT MADE)' |                         | 09 Oct 2020 00:02:10 |

**US3642217**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 08 Dec 2020 18:29:07 |
| User entered empty.       |                         | 09 Oct 2020 00:02:10 |

**US3642217**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:29:12 |
| User entered 'Yes (Y)'    |                             | 09 Oct 2020 00:02:16 |

**US3642217**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'I'  | System           | 09 Oct 2020 00:02:16 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Was this visit performed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:29:34 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 13 Oct 2020 22:13:37 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:29:34 |
| User entered '13 Oct 2020' | Megan Loughran (b) (4)<br>(b) (4) | 13 Oct 2020 22:13:37 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:16:22

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded.      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:29:34 |
| User entered 'Clinic (Clinic)' | Megan Loughran (b) (4)<br>(b) (4) | 13 Oct 2020 22:13:37 |



**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'VISIT2' | System           | 13 Oct 2020 22:13:37 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Son Do (b) (4)   | 15 Oct 2020 17:49:03 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:29 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:29 |
| User entered '13 Oct 2020' | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:29 |
| User entered '13:58'      | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered '13 Oct 2020 13:58' | System           | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:29 |
| User entered '99.1' F     | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:29 |
| User entered 'Oral (Oral)' | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |



**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:29 |
| User entered empty.       | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:29 |
| User entered '72'         | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'bpm' | System           | 15 Oct 2020 17:49:03 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:29 |
| User entered '16'         | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'breaths/min' | System           | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:29 |
| User entered '135'        | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'mmHg' | System           | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:29 |
| User entered '75'         | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |



US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:16:22

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'mmHg' | System           | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Son Do (b) (4)   | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:32 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:32 |
| User entered '13 Oct 2020' | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:32 |
| User entered '16:27'      | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered '13 Oct 2020 16:27' | System           | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:32 |
| User entered '98.1' F     | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:32 |
| User entered 'Oral (Oral)' | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |



**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:32 |
| User entered empty.       | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:32 |
| User entered '63'         | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'bpm' | System           | 15 Oct 2020 17:49:03 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:32 |
| User entered '17'         | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'breaths/min' | System           | 15 Oct 2020 17:49:03 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:32 |
| User entered '127'        | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:16:22

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'mmHg' | System           | 15 Oct 2020 17:49:03 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:32 |
| User entered '70'         | Son Do (b) (4)              | 15 Oct 2020 17:49:03 |



**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'mmHg' | System           | 15 Oct 2020 17:49:03 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:16:22

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:40 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 15 Oct 2020 17:49:15 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:16:22**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:54:40 |
| User entered '13 Oct 2020' | Son Do (b) (4)              | 15 Oct 2020 17:49:15 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

[Was study treatment given?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:54:59 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:16:22**

[If No, reason not given](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:54:59 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 13 Oct 2020 23:05:04 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

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)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:54:59 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 13 Oct 2020 23:05:04 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:54:59 |
| User entered '13 Oct 2020' | Megan Loughran (b) (4)<br>(b) (4) | 13 Oct 2020 23:05:04 |



**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:16:22**

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:54:59 |
| User entered '15:56'      | Megan Loughran (b) (4)<br>(b) (4) | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:16:22**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered '13 Oct 2020 15:56' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

[Which arm was used to give treatment?](#)

| Audit                                | User                              | Time (GMT)           |
|--------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)                  | 27 Mar 2021 09:39:53 |
| User signature succeeded.            | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:59 |
| DataPoint Verified.                  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:54:59 |
| User entered 'Right Arm (RIGHT ARM)' | Megan Loughran (b) (4)<br>(b) (4) | 13 Oct 2020 23:05:04 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| DataPoint Verified. |                  | 08 Dec 2020 18:54:59 |
| User entered 'ONCE' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:16:22

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'INTRAMUSCULAR' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:55:05 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 15 Oct 2020 17:49:25 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:55:05 |
| User entered '13 Oct 2020' | Son Do (b) (4)              | 15 Oct 2020 17:49:25 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:55:05 |
| User entered '15:42'      | Son Do (b) (4)              | 15 Oct 2020 17:49:25 |



**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered '13 Oct 2020 15:42' | System           | 15 Oct 2020 17:49:25 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:16:22

Collection date (dd MMM yyyy)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:55:12 |
| User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).             | System                      | 15 Oct 2020 17:52:49 |
| Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System). | System                      | 15 Oct 2020 17:52:49 |
| User entered '13 Oct 2020' reason for change: Data Entry Error  | Son Do (b) (4)              | 15 Oct 2020 17:52:49 |
| User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).             | System                      | 15 Oct 2020 17:52:41 |
| User entered empty.   | Son Do (b) (4)              | 15 Oct 2020 17:52:41 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Son Do (b) (4)   | 15 Oct 2020 17:52:41 |

US3642217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:16:22

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:55:12 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 15 Oct 2020 17:52:41 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:55:12 |
| User entered '15:45'      | Son Do (b) (4)              | 15 Oct 2020 17:52:41 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered '13 Oct 2020 15:45' | System           | 15 Oct 2020 17:52:49 |
| User entered empty.              | System           | 15 Oct 2020 17:52:41 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Lab Test](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)' | (b) (4)          | 15 Oct 2020 17:52:41 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:55:12 |
| User entered 'No (N)'     | Son Do (b) (4)              | 15 Oct 2020 17:52:41 |



**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:16:22**

**Collection time (00:00 - 23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:55:12 |
| User entered empty.       | Son Do (b) (4)              | 15 Oct 2020 17:52:41 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered empty. | System           | 15 Oct 2020 17:52:41 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:55:19 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 15 Oct 2020 17:52:54 |

**US3642217**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'I'  | System           | 15 Oct 2020 17:52:54 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:26:31', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '90182324-48d6-4a10-841f-1b41f73a23d1' | System           | 13 Oct 2020 23:26:58 |
| User entered 'Yes (Y)'   | System           | 13 Oct 2020 23:26:58 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:26:39', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '90182324-48d6-4a10-841f-1b41f73a23d1' | System           | 13 Oct 2020 23:26:58 |
| User entered '98.1'  | System           | 13 Oct 2020 23:26:58 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:26:46', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '90182324-48d6-4a10-841f-1b41f73a23d1' | System           | 13 Oct 2020 23:26:58 |
| User entered 'No (N)'  | System           | 13 Oct 2020 23:26:58 |



**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:26:55', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '90182324-48d6-4a10-841f-1b41f73a23d1' | System           | 13 Oct 2020 23:26:58 |
| User entered '13 Oct 2020 16:26'   | System           | 13 Oct 2020 23:26:58 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '13 Oct 2020 16:16' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '13 Oct 2020 18:46' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.                                | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 1, after vaccination (at home)' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:01:46', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'bb887864-67be-44eb-bb95-886e7d423fa6' | System           | 14 Oct 2020 06:02:14 |
| User entered 'Yes (Y)'   | System           | 14 Oct 2020 06:02:14 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:01:56', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'bb887864-67be-44eb-bb95-886e7d423fa6' | System           | 14 Oct 2020 06:02:14 |
| User entered '97.6'  | System           | 14 Oct 2020 06:02:14 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:02:01', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'bb887864-67be-44eb-bb95-886e7d423fa6' | System           | 14 Oct 2020 06:02:14 |
| User entered 'No (N)'  | System           | 14 Oct 2020 06:02:14 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:02:12', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'bb887864-67be-44eb-bb95-886e7d423fa6' | System           | 14 Oct 2020 06:02:14 |
| User entered '13 Oct 2020 23:02'   | System           | 14 Oct 2020 06:02:14 |



US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '13 Oct 2020 19:41' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '14 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 2' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:41:41', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '5d0a7bcb-00d7-4e81-85d6-de6d672521f4' | System           | 15 Oct 2020 01:42:09 |
| User entered 'Yes (Y)'   | System           | 15 Oct 2020 01:42:09 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:41:47', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '5d0a7bcb-00d7-4e81-85d6-de6d672521f4' | System           | 15 Oct 2020 01:42:09 |
| User entered '98.6'  | System           | 15 Oct 2020 01:42:09 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:41:58', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '5d0a7bcb-00d7-4e81-85d6-de6d672521f4' | System           | 15 Oct 2020 01:42:09 |
| User entered 'No (N)'  | System           | 15 Oct 2020 01:42:09 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:42:04', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '5d0a7bcb-00d7-4e81-85d6-de6d672521f4' | System           | 15 Oct 2020 01:42:09 |
| User entered '14 Oct 2020 18:42'   | System           | 15 Oct 2020 01:42:09 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '14 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |



**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 3' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:48:33', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '742aec53-cae7-41cd-a2d6-c4053038ca3e' | System           | 16 Oct 2020 02:48:50 |
| User entered 'Yes (Y)'   | System           | 16 Oct 2020 02:48:50 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:48:38', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '742aec53-cae7-41cd-a2d6-c4053038ca3e' User entered '99.2' | System           | 16 Oct 2020 02:48:50 |
|  | System           | 16 Oct 2020 02:48:50 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:48:41', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '742aec53-cae7-41cd-a2d6-c4053038ca3e' | System           | 16 Oct 2020 02:48:50 |
| User entered 'No (N)'  | System           | 16 Oct 2020 02:48:50 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:48:46', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '742aec53-cae7-41cd-a2d6-c4053038ca3e' | System           | 16 Oct 2020 02:48:50 |
| User entered '15 Oct 2020 19:48'   | System           | 16 Oct 2020 02:48:50 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '16 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |



US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 4' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:43:33', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'd32853b8-f332-4ece-bb8f-a0bd1e88382a' | System           | 17 Oct 2020 04:43:58 |
| User entered 'Yes (Y)'   | System           | 17 Oct 2020 04:43:58 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:43:41', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'd32853b8-f332-4ece-bb8f-a0bd1e88382a' | System           | 17 Oct 2020 04:43:58 |
| User entered '98.0'  | System           | 17 Oct 2020 04:43:58 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:43:45', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'd32853b8-f332-4ece-bb8f-a0bd1e88382a' | System           | 17 Oct 2020 04:43:58 |
| User entered 'No (N)'  | System           | 17 Oct 2020 04:43:58 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:43:50', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'd32853b8-f332-4ece-bb8f-a0bd1e88382a' | System           | 17 Oct 2020 04:43:58 |
| User entered '16 Oct 2020 21:43'   | System           | 17 Oct 2020 04:43:58 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:16:22

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '16 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '17 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 5' | System           | 13 Oct 2020 23:05:04 |



US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:46:37', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '13b2bb59-fccd-4f7b-9257-527e975911ba' | System           | 18 Oct 2020 04:47:02 |
| User entered 'Yes (Y)'   | System           | 18 Oct 2020 04:47:02 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:46:43', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '13b2bb59-fccd-4f7b-9257-527e975911ba' | System           | 18 Oct 2020 04:47:02 |
| User entered '96.5'  | System           | 18 Oct 2020 04:47:02 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:46:47', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '13b2bb59-fccd-4f7b-9257-527e975911ba' | System           | 18 Oct 2020 04:47:02 |
| User entered 'No (N)'  | System           | 18 Oct 2020 04:47:02 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:46:57', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '13b2bb59-fccd-4f7b-9257-527e975911ba' | System           | 18 Oct 2020 04:47:02 |
| User entered '17 Oct 2020 21:46'   | System           | 18 Oct 2020 04:47:02 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '17 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '18 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 6' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:04:26', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '2117795b-06bb-4193-9e21-1a2d3cffbf6f' | System           | 19 Oct 2020 02:04:43 |
| User entered 'Yes (Y)'   | System           | 19 Oct 2020 02:04:43 |



US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:04:32', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '2117795b-06bb-4193-9e21-1a2d3cffbf6f' | System           | 19 Oct 2020 02:04:43 |
| User entered '97.7'  | System           | 19 Oct 2020 02:04:43 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:04:37', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '2117795b-06bb-4193-9e21-1a2d3cffbf6f' | System           | 19 Oct 2020 02:04:43 |
| User entered 'No (N)'  | System           | 19 Oct 2020 02:04:43 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:04:41', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '2117795b-06bb-4193-9e21-1a2d3cffbf6f' | System           | 19 Oct 2020 02:04:43 |
| User entered '18 Oct 2020 19:04'   | System           | 19 Oct 2020 02:04:43 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '18 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '19 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 7' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:35:58', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '53358e23-8ddf-4315-8b4e-bd439ffbcff2' | System           | 20 Oct 2020 02:36:49 |
| User entered 'Yes (Y)'   | System           | 20 Oct 2020 02:36:49 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:36:18', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '53358e23-8ddf-4315-8b4e-bd439ffbcff2' | System           | 20 Oct 2020 02:36:49 |
| User entered '98.7'  | System           | 20 Oct 2020 02:36:49 |



US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:36:24', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '53358e23-8ddf-4315-8b4e-bd439ffbcff2' | System           | 20 Oct 2020 02:36:49 |
| User entered 'Yes (Y)'   | System           | 20 Oct 2020 02:36:49 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

To **TREAT** pain or fever that has already occurred

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 25 Feb 2021 13:09:40 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PARTICIPANT WAS CONTACTED BY STUDY STAFF - SEE SAFETY CALL SOURCE DOC FOR ADDITIONAL INFORMATION.' (Site from System). | Colleen McLellan (b) (4) | 19 Nov 2020 06:07:32 |
| 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 Oct 2020 02:36:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:36:37', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '53358e23-8ddf-4315-8b4e-bd439ffbcff2'  | System                   | 20 Oct 2020 02:36:49 |
| User entered '1'  | System                   | 20 Oct 2020 02:36:49 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:16:22

To **PREVENT** pain or fever from occurring

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:36:37', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '53358e23-8ddf-4315-8b4e-bd439ffbcff2' | System           | 20 Oct 2020 02:36:49 |
| User entered '0'   | System           | 20 Oct 2020 02:36:49 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:36:45', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '53358e23-8ddf-4315-8b4e-bd439ffbcff2' | System           | 20 Oct 2020 02:36:49 |
| User entered '19 Oct 2020 19:36'   | System           | 20 Oct 2020 02:36:49 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '19 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '20 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 20 Oct 2020 02:36:49 |
| User entered 'Day 8' | System           | 20 Oct 2020 02:36:49 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |



US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:16:22

To **TREAT** pain or fever that has already occurred

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:16:22

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:16:22

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '20 Oct 2020 12:00' | System           | 20 Oct 2020 02:36:49 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '21 Oct 2020 11:59' | System           | 20 Oct 2020 02:36:49 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 20 Oct 2020 02:36:49 |
| User entered 'Day 9' | System           | 20 Oct 2020 02:36:49 |



US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:16:22

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:16:22

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:16:22

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:16:22

To **TREAT** pain or fever that has already occurred

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:16:22

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

US3642217

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:16:22

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '21 Oct 2020 12:00' | System           | 20 Oct 2020 02:36:49 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '22 Oct 2020 11:59' | System           | 20 Oct 2020 02:36:49 |



US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:27:38', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c619c61e-88c9-4874-ba96-6c1923828fec' | System           | 13 Oct 2020 23:28:45 |
| User entered 'None (1)'  | System           | 13 Oct 2020 23:28:45 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:27:44', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c619c61e-88c9-4874-ba96-6c1923828fec' | System           | 13 Oct 2020 23:28:45 |
| User entered 'No (N)'  | System           | 13 Oct 2020 23:28:45 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:27:48', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c619c61e-88c9-4874-ba96-6c1923828fec' | System           | 13 Oct 2020 23:28:45 |
| User entered 'No (N)'  | System           | 13 Oct 2020 23:28:45 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:28:35', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c619c61e-88c9-4874-ba96-6c1923828fec' | System           | 13 Oct 2020 23:28:45 |
| User entered 'None (1)'  | System           | 13 Oct 2020 23:28:45 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:28:40', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c619c61e-88c9-4874-ba96-6c1923828fec' | System           | 13 Oct 2020 23:28:45 |
| User entered '13 Oct 2020 16:28'   | System           | 13 Oct 2020 23:28:45 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '13 Oct 2020 16:16' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '13 Oct 2020 18:46' | System           | 13 Oct 2020 23:05:04 |



US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.                                | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 1, after vaccination (at home)' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:02:19', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c0eb7d01-bddc-4ea2-b86f-d0417b4f5190' | System           | 14 Oct 2020 06:02:51 |
| User entered 'None (1)'  | System           | 14 Oct 2020 06:02:51 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:02:23', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c0eb7d01-bddc-4ea2-b86f-d0417b4f5190' | System           | 14 Oct 2020 06:02:51 |
| User entered 'No (N)'  | System           | 14 Oct 2020 06:02:51 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:02:31', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c0eb7d01-bddc-4ea2-b86f-d0417b4f5190' | System           | 14 Oct 2020 06:02:51 |
| User entered 'No (N)'  | System           | 14 Oct 2020 06:02:51 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:02:38', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c0eb7d01-bddc-4ea2-b86f-d0417b4f5190' | System           | 14 Oct 2020 06:02:51 |
| User entered 'None (1)'  | System           | 14 Oct 2020 06:02:51 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:02:43', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c0eb7d01-bddc-4ea2-b86f-d0417b4f5190' | System           | 14 Oct 2020 06:02:51 |
| User entered '13 Oct 2020 23:02'   | System           | 14 Oct 2020 06:02:51 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '13 Oct 2020 19:41' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '14 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |



US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 2' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:48:39', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '245837f6-7b28-4cf4-80d1-e28eda7ffc92' | System           | 15 Oct 2020 01:49:11 |
| User entered 'Does not interfere with activity (2)'  | System           | 15 Oct 2020 01:49:11 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:48:42', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '245837f6-7b28-4cf4-80d1-e28eda7ffc92' | System           | 15 Oct 2020 01:49:11 |
| User entered 'No (N)'  | System           | 15 Oct 2020 01:49:11 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:48:45', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '245837f6-7b28-4cf4-80d1-e28eda7ffc92' | System           | 15 Oct 2020 01:49:11 |
| User entered 'No (N)'  | System           | 15 Oct 2020 01:49:11 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:48:53', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '245837f6-7b28-4cf4-80d1-e28eda7ffc92' | System           | 15 Oct 2020 01:49:11 |
| User entered 'None (1)'  | System           | 15 Oct 2020 01:49:11 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:49:02', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '245837f6-7b28-4cf4-80d1-e28eda7ffc92' | System           | 15 Oct 2020 01:49:11 |
| User entered '14 Oct 2020 18:49'   | System           | 15 Oct 2020 01:49:11 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '14 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |



US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 3' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:48:57', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91bb78d5-a05f-476f-be7e-7c6002c463ee' | System           | 16 Oct 2020 02:49:29 |
| User entered 'Does not interfere with activity (2)'  | System           | 16 Oct 2020 02:49:29 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:49:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91bb78d5-a05f-476f-be7e-7c6002c463ee' | System           | 16 Oct 2020 02:49:29 |
| User entered 'No (N)'  | System           | 16 Oct 2020 02:49:29 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:49:14', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91bb78d5-a05f-476f-be7e-7c6002c463ee' | System           | 16 Oct 2020 02:49:29 |
| User entered 'No (N)'  | System           | 16 Oct 2020 02:49:29 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:49:19', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91bb78d5-a05f-476f-be7e-7c6002c463ee' | System           | 16 Oct 2020 02:49:29 |
| User entered 'None (1)'  | System           | 16 Oct 2020 02:49:29 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:49:26', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91bb78d5-a05f-476f-be7e-7c6002c463ee' | System           | 16 Oct 2020 02:49:29 |
| User entered '15 Oct 2020 19:49'   | System           | 16 Oct 2020 02:49:29 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '16 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |



US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 4' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:43:57', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'dece9ab8-e592-45b7-8037-dafb2065dd48' | System           | 17 Oct 2020 04:44:28 |
| User entered 'None (1)'  | System           | 17 Oct 2020 04:44:28 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Is there any **REDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:44:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'dece9ab8-e592-45b7-8037-dafb2065dd48' | System           | 17 Oct 2020 04:44:28 |
| User entered 'No (N)'  | System           | 17 Oct 2020 04:44:28 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:44:09', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'dece9ab8-e592-45b7-8037-dafb2065dd48' | System           | 17 Oct 2020 04:44:28 |
| User entered 'No (N)'  | System           | 17 Oct 2020 04:44:28 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:44:17', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'dece9ab8-e592-45b7-8037-dafb2065dd48' | System           | 17 Oct 2020 04:44:28 |
| User entered 'None (1)'  | System           | 17 Oct 2020 04:44:28 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:44:23', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'dece9ab8-e592-45b7-8037-dafb2065dd48' | System           | 17 Oct 2020 04:44:28 |
| User entered '16 Oct 2020 21:44'   | System           | 17 Oct 2020 04:44:28 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '16 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '17 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |



US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 5' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:47:12', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '7a23e921-1af9-4d43-99d3-238eccf8e04f' | System           | 18 Oct 2020 04:47:52 |
| User entered 'None (1)'  | System           | 18 Oct 2020 04:47:52 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:47:17', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '7a23e921-1af9-4d43-99d3-238eccf8e04f' | System           | 18 Oct 2020 04:47:52 |
| User entered 'No (N)'  | System           | 18 Oct 2020 04:47:52 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:47:25', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '7a23e921-1af9-4d43-99d3-238eccf8e04f' | System           | 18 Oct 2020 04:47:52 |
| User entered 'No (N)'  | System           | 18 Oct 2020 04:47:52 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:47:34', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '7a23e921-1af9-4d43-99d3-238eccf8e04f' | System           | 18 Oct 2020 04:47:52 |
| User entered 'None (1)'  | System           | 18 Oct 2020 04:47:52 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:47:50', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '7a23e921-1af9-4d43-99d3-238eccf8e04f' | System           | 18 Oct 2020 04:47:52 |
| User entered '17 Oct 2020 21:47'   | System           | 18 Oct 2020 04:47:52 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '17 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '18 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |



US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 6' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:04:45', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '71274252-c8c8-408b-878c-dfb74489bbd9' | System           | 19 Oct 2020 02:05:16 |
| User entered 'None (1)'  | System           | 19 Oct 2020 02:05:16 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:04:49', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '71274252-c8c8-408b-878c-dfb74489bbd9' | System           | 19 Oct 2020 02:05:16 |
| User entered 'No (N)'  | System           | 19 Oct 2020 02:05:16 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:04:53', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '71274252-c8c8-408b-878c-dfb74489bbd9' | System           | 19 Oct 2020 02:05:16 |
| User entered 'No (N)'  | System           | 19 Oct 2020 02:05:16 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:04:57', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '71274252-c8c8-408b-878c-dfb74489bbd9' | System           | 19 Oct 2020 02:05:16 |
| User entered 'None (1)'  | System           | 19 Oct 2020 02:05:16 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:05:11', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '71274252-c8c8-408b-878c-dfb74489bbd9' | System           | 19 Oct 2020 02:05:16 |
| User entered '18 Oct 2020 19:05'   | System           | 19 Oct 2020 02:05:16 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '18 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '19 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |



US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 7' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:36:50', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'a15ed0c2-c3bd-43fb-87e9-e7b78c2985f7' | System           | 20 Oct 2020 02:37:07 |
| User entered 'None (1)'  | System           | 20 Oct 2020 02:37:07 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:36:53', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'a15ed0c2-c3bd-43fb-87e9-e7b78c2985f7' | System           | 20 Oct 2020 02:37:07 |
| User entered 'No (N)'  | System           | 20 Oct 2020 02:37:07 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:36:55', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'a15ed0c2-c3bd-43fb-87e9-e7b78c2985f7' | System           | 20 Oct 2020 02:37:07 |
| User entered 'No (N)'  | System           | 20 Oct 2020 02:37:07 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:36:58', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'a15ed0c2-c3bd-43fb-87e9-e7b78c2985f7' | System           | 20 Oct 2020 02:37:07 |
| User entered 'None (1)'  | System           | 20 Oct 2020 02:37:07 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:37:04', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'a15ed0c2-c3bd-43fb-87e9-e7b78c2985f7' | System           | 20 Oct 2020 02:37:07 |
| User entered '19 Oct 2020 19:37'   | System           | 20 Oct 2020 02:37:07 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '19 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:16:22

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '20 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |



US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:28:46', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '933553c7-cbed-4df3-b672-398e0b2f9965' | System           | 13 Oct 2020 23:29:17 |
| User entered 'None (0)'  | System           | 13 Oct 2020 23:29:17 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:28:50', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '933553c7-cbed-4df3-b672-398e0b2f9965' | System           | 13 Oct 2020 23:29:17 |
| User entered 'None (0)'  | System           | 13 Oct 2020 23:29:17 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:28:53', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '933553c7-cbed-4df3-b672-398e0b2f9965' | System           | 13 Oct 2020 23:29:17 |
| User entered 'None (0)'  | System           | 13 Oct 2020 23:29:17 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:28:56', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '933553c7-cbed-4df3-b672-398e0b2f9965' | System           | 13 Oct 2020 23:29:17 |
| User entered 'None (0)'  | System           | 13 Oct 2020 23:29:17 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:28:59', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '933553c7-cbed-4df3-b672-398e0b2f9965' | System           | 13 Oct 2020 23:29:17 |
| User entered 'None (0)'  | System           | 13 Oct 2020 23:29:17 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:29:02', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '933553c7-cbed-4df3-b672-398e0b2f9965' | System           | 13 Oct 2020 23:29:17 |
| User entered 'None (0)'  | System           | 13 Oct 2020 23:29:17 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:29:07', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '933553c7-cbed-4df3-b672-398e0b2f9965' | System           | 13 Oct 2020 23:29:17 |
| User entered 'No (N)'  | System           | 13 Oct 2020 23:29:17 |



**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T16:29:12', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '933553c7-cbed-4df3-b672-398e0b2f9965' | System           | 13 Oct 2020 23:29:17 |
| User entered '13 Oct 2020 16:29'   | System           | 13 Oct 2020 23:29:17 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '13 Oct 2020 16:16' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '13 Oct 2020 18:46' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.                                | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 1, after vaccination (at home)' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:02:49', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '718e825f-38c2-4a96-b473-b36c04f51b8d' | System           | 14 Oct 2020 06:03:23 |
| User entered 'None (0)'  | System           | 14 Oct 2020 06:03:23 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:02:52', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '718e825f-38c2-4a96-b473-b36c04f51b8d' | System           | 14 Oct 2020 06:03:23 |
| User entered 'None (0)'  | System           | 14 Oct 2020 06:03:23 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:02:55', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '718e825f-38c2-4a96-b473-b36c04f51b8d' | System           | 14 Oct 2020 06:03:23 |
| User entered 'None (0)'  | System           | 14 Oct 2020 06:03:23 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:02:58', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '718e825f-38c2-4a96-b473-b36c04f51b8d' | System           | 14 Oct 2020 06:03:23 |
| User entered 'None (0)'  | System           | 14 Oct 2020 06:03:23 |



US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:03:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '718e825f-38c2-4a96-b473-b36c04f51b8d' | System           | 14 Oct 2020 06:03:23 |
| User entered 'None (0)'  | System           | 14 Oct 2020 06:03:23 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:03:03', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '718e825f-38c2-4a96-b473-b36c04f51b8d' | System           | 14 Oct 2020 06:03:23 |
| User entered 'None (0)'  | System           | 14 Oct 2020 06:03:23 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:03:12', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '718e825f-38c2-4a96-b473-b36c04f51b8d' | System           | 14 Oct 2020 06:03:23 |
| User entered 'No (N)'  | System           | 14 Oct 2020 06:03:23 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-13T23:03:21', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '718e825f-38c2-4a96-b473-b36c04f51b8d' | System           | 14 Oct 2020 06:03:23 |
| User entered '13 Oct 2020 23:03'   | System           | 14 Oct 2020 06:03:23 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '13 Oct 2020 19:41' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '14 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 2' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:49:08', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '197a44bc-0fcf-44d8-ad9f-74a5552dc3f6' | System           | 15 Oct 2020 01:49:58 |
| User entered 'None (0)'  | System           | 15 Oct 2020 01:49:58 |



US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:49:29', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '197a44bc-0fcf-44d8-ad9f-74a5552dc3f6' | System           | 15 Oct 2020 01:49:58 |
| User entered 'None (0)'  | System           | 15 Oct 2020 01:49:58 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:49:32', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '197a44bc-0fcf-44d8-ad9f-74a5552dc3f6' | System           | 15 Oct 2020 01:49:58 |
| User entered 'None (0)'  | System           | 15 Oct 2020 01:49:58 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:49:36', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '197a44bc-0fcf-44d8-ad9f-74a5552dc3f6' | System           | 15 Oct 2020 01:49:58 |
| User entered 'None (0)'  | System           | 15 Oct 2020 01:49:58 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:49:39', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '197a44bc-0fcf-44d8-ad9f-74a5552dc3f6' | System           | 15 Oct 2020 01:49:58 |
| User entered 'None (0)'  | System           | 15 Oct 2020 01:49:58 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:49:41', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '197a44bc-0fcf-44d8-ad9f-74a5552dc3f6' | System           | 15 Oct 2020 01:49:58 |
| User entered 'None (0)'  | System           | 15 Oct 2020 01:49:58 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:49:47', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '197a44bc-0fcf-44d8-ad9f-74a5552dc3f6' | System           | 15 Oct 2020 01:49:58 |
| User entered 'No (N)'  | System           | 15 Oct 2020 01:49:58 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:16:22

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-14T18:49:52', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '197a44bc-0fcf-44d8-ad9f-74a5552dc3f6' | System           | 15 Oct 2020 01:49:58 |
| User entered '14 Oct 2020 18:49'   | System           | 15 Oct 2020 01:49:58 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '14 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |



**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 3' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:49:32', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91393210-0e0f-4094-adb7-815166bf2275' | System           | 16 Oct 2020 02:50:09 |
| User entered 'None (0)'  | System           | 16 Oct 2020 02:50:09 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:49:34', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91393210-0e0f-4094-adb7-815166bf2275' | System           | 16 Oct 2020 02:50:09 |
| User entered 'None (0)'  | System           | 16 Oct 2020 02:50:09 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:49:37', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91393210-0e0f-4094-adb7-815166bf2275' | System           | 16 Oct 2020 02:50:09 |
| User entered 'None (0)'  | System           | 16 Oct 2020 02:50:09 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:49:41', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91393210-0e0f-4094-adb7-815166bf2275' | System           | 16 Oct 2020 02:50:09 |
| User entered 'None (0)'  | System           | 16 Oct 2020 02:50:09 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:49:43', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91393210-0e0f-4094-adb7-815166bf2275' | System           | 16 Oct 2020 02:50:09 |
| User entered 'None (0)'  | System           | 16 Oct 2020 02:50:09 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:49:45', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91393210-0e0f-4094-adb7-815166bf2275' | System           | 16 Oct 2020 02:50:09 |
| User entered 'None (0)'  | System           | 16 Oct 2020 02:50:09 |



US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:50:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91393210-0e0f-4094-adb7-815166bf2275' | System           | 16 Oct 2020 02:50:09 |
| User entered 'No (N)'  | System           | 16 Oct 2020 02:50:09 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-15T19:50:04', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '91393210-0e0f-4094-adb7-815166bf2275' | System           | 16 Oct 2020 02:50:09 |
| User entered '15 Oct 2020 19:50'   | System           | 16 Oct 2020 02:50:09 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '15 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '16 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 4' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:44:27', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '16b3be88-58e9-41de-9445-082222c73975' | System           | 17 Oct 2020 04:44:55 |
| User entered 'None (0)'  | System           | 17 Oct 2020 04:44:55 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:44:30', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '16b3be88-58e9-41de-9445-082222c73975' | System           | 17 Oct 2020 04:44:55 |
| User entered 'None (0)'  | System           | 17 Oct 2020 04:44:55 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:44:33', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '16b3be88-58e9-41de-9445-082222c73975' | System           | 17 Oct 2020 04:44:55 |
| User entered 'None (0)'  | System           | 17 Oct 2020 04:44:55 |



US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:44:36', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '16b3be88-58e9-41de-9445-082222c73975' | System           | 17 Oct 2020 04:44:55 |
| User entered 'None (0)'  | System           | 17 Oct 2020 04:44:55 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:44:39', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '16b3be88-58e9-41de-9445-082222c73975' | System           | 17 Oct 2020 04:44:55 |
| User entered 'None (0)'  | System           | 17 Oct 2020 04:44:55 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:44:41', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '16b3be88-58e9-41de-9445-082222c73975' | System           | 17 Oct 2020 04:44:55 |
| User entered 'None (0)'  | System           | 17 Oct 2020 04:44:55 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:44:44', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '16b3be88-58e9-41de-9445-082222c73975' | System           | 17 Oct 2020 04:44:55 |
| User entered 'No (N)'  | System           | 17 Oct 2020 04:44:55 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-16T21:44:52', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '16b3be88-58e9-41de-9445-082222c73975' | System           | 17 Oct 2020 04:44:55 |
| User entered '16 Oct 2020 21:44'   | System           | 17 Oct 2020 04:44:55 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '16 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '17 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 5' | System           | 13 Oct 2020 23:05:04 |



US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:47:54', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '22f05a6b-9102-4ac3-803e-7b320efbe2f7' | System           | 18 Oct 2020 04:48:26 |
| User entered 'None (0)'  | System           | 18 Oct 2020 04:48:26 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:48:02', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '22f05a6b-9102-4ac3-803e-7b320efbe2f7' | System           | 18 Oct 2020 04:48:26 |
| User entered 'None (0)'  | System           | 18 Oct 2020 04:48:26 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:48:04', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '22f05a6b-9102-4ac3-803e-7b320efbe2f7' | System           | 18 Oct 2020 04:48:26 |
| User entered 'None (0)'  | System           | 18 Oct 2020 04:48:26 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:48:07', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '22f05a6b-9102-4ac3-803e-7b320efbe2f7' | System           | 18 Oct 2020 04:48:26 |
| User entered 'None (0)'  | System           | 18 Oct 2020 04:48:26 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:48:11', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '22f05a6b-9102-4ac3-803e-7b320efbe2f7' | System           | 18 Oct 2020 04:48:26 |
| User entered 'None (0)'  | System           | 18 Oct 2020 04:48:26 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:48:13', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '22f05a6b-9102-4ac3-803e-7b320efbe2f7' | System           | 18 Oct 2020 04:48:26 |
| User entered 'None (0)'  | System           | 18 Oct 2020 04:48:26 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:48:17', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '22f05a6b-9102-4ac3-803e-7b320efbe2f7' | System           | 18 Oct 2020 04:48:26 |
| User entered 'No (N)'  | System           | 18 Oct 2020 04:48:26 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-17T21:48:24', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '22f05a6b-9102-4ac3-803e-7b320efbe2f7' | System           | 18 Oct 2020 04:48:26 |
| User entered '17 Oct 2020 21:48'   | System           | 18 Oct 2020 04:48:26 |



**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '17 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '18 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 6' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:05:17', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8492cb6-1201-4c03-973e-b0e6d43e4bb6' | System           | 19 Oct 2020 02:05:44 |
| User entered 'None (0)'  | System           | 19 Oct 2020 02:05:44 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:05:22', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8492cb6-1201-4c03-973e-b0e6d43e4bb6' | System           | 19 Oct 2020 02:05:44 |
| User entered 'None (0)'  | System           | 19 Oct 2020 02:05:44 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:05:25', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8492cb6-1201-4c03-973e-b0e6d43e4bb6' | System           | 19 Oct 2020 02:05:44 |
| User entered 'None (0)'  | System           | 19 Oct 2020 02:05:44 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:05:27', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8492cb6-1201-4c03-973e-b0e6d43e4bb6' | System           | 19 Oct 2020 02:05:44 |
| User entered 'None (0)'  | System           | 19 Oct 2020 02:05:44 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:05:29', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8492cb6-1201-4c03-973e-b0e6d43e4bb6' | System           | 19 Oct 2020 02:05:44 |
| User entered 'None (0)'  | System           | 19 Oct 2020 02:05:44 |



US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:05:32', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8492cb6-1201-4c03-973e-b0e6d43e4bb6' | System           | 19 Oct 2020 02:05:44 |
| User entered 'None (0)'  | System           | 19 Oct 2020 02:05:44 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:05:36', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8492cb6-1201-4c03-973e-b0e6d43e4bb6' | System           | 19 Oct 2020 02:05:44 |
| User entered 'No (N)'  | System           | 19 Oct 2020 02:05:44 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-18T19:05:42', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8492cb6-1201-4c03-973e-b0e6d43e4bb6' | System           | 19 Oct 2020 02:05:44 |
| User entered '18 Oct 2020 19:05'   | System           | 19 Oct 2020 02:05:44 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '18 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '19 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 13 Oct 2020 23:05:04 |
| User entered 'Day 7' | System           | 13 Oct 2020 23:05:04 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:37:09', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fa8c5147-f99a-43cc-85d0-cfdce23a6e04' | System           | 20 Oct 2020 02:37:48 |
| User entered 'None (0)'  | System           | 20 Oct 2020 02:37:48 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:37:12', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fa8c5147-f99a-43cc-85d0-cfdce23a6e04' | System           | 20 Oct 2020 02:37:48 |
| User entered 'None (0)'  | System           | 20 Oct 2020 02:37:48 |



US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:37:14', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fa8c5147-f99a-43cc-85d0-cfdce23a6e04' | System           | 20 Oct 2020 02:37:48 |
| User entered 'None (0)'  | System           | 20 Oct 2020 02:37:48 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:37:17', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fa8c5147-f99a-43cc-85d0-cfdce23a6e04' | System           | 20 Oct 2020 02:37:48 |
| User entered 'None (0)'  | System           | 20 Oct 2020 02:37:48 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:37:19', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fa8c5147-f99a-43cc-85d0-cfdce23a6e04' | System           | 20 Oct 2020 02:37:48 |
| User entered 'None (0)'  | System           | 20 Oct 2020 02:37:48 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:37:21', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fa8c5147-f99a-43cc-85d0-cfdce23a6e04' | System           | 20 Oct 2020 02:37:48 |
| User entered 'None (0)'  | System           | 20 Oct 2020 02:37:48 |

US3642217

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:37:30', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fa8c5147-f99a-43cc-85d0-cfdce23a6e04' | System           | 20 Oct 2020 02:37:48 |
| User entered 'No (N)'  | System           | 20 Oct 2020 02:37:48 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-10-19T19:37:42', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fa8c5147-f99a-43cc-85d0-cfdce23a6e04' | System           | 20 Oct 2020 02:37:48 |
| User entered '19 Oct 2020 19:37'   | System           | 20 Oct 2020 02:37:48 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '19 Oct 2020 12:00' | System           | 13 Oct 2020 23:05:04 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '20 Oct 2020 11:59' | System           | 13 Oct 2020 23:05:04 |



US3642217

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 20 Oct 2020 02:36:49 |
| User entered 'Day 8' | System           | 20 Oct 2020 02:36:49 |

US3642217

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '20 Oct 2020 12:00' | System           | 20 Oct 2020 02:36:49 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '21 Oct 2020 11:59' | System           | 20 Oct 2020 02:36:49 |

US3642217

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:16:22

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.   | System           | 20 Oct 2020 02:36:49 |
| User entered 'Day 9' | System           | 20 Oct 2020 02:36:49 |

US3642217

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:16:22

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) | 25 Feb 2021 13:09:40 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
|                   |                  |                      |



**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '21 Oct 2020 12:00' | System           | 20 Oct 2020 02:36:49 |

**US3642217**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:16:22**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| User entered '22 Oct 2020 11:59' | System           | 20 Oct 2020 02:36:49 |

**US3642217**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Was Contact Attempted?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:12:15 |
| User entered 'Yes (Y)'    | Jennifer Morales (b) (4)<br>(b) (4) | 20 Oct 2020 17:20:58 |

**US3642217**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:12:15 |
| User entered '20 Oct 2020' | Jennifer Morales (b) (4)<br>(b) (4) | 20 Oct 2020 17:20:58 |

**US3642217**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded.                  | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                        | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:12:15 |
| User entered 'Contact Made (CONTACT MADE)' | Jennifer Morales (b) (4)<br>(b) (4) | 20 Oct 2020 17:20:58 |

**US3642217**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:12:15 |
| User entered empty.       | Jennifer Morales (b) (4)<br>(b) (4) | 20 Oct 2020 17:20:58 |

**US3642217**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:12:20 |
| User entered 'Yes (Y)'    | Jennifer Morales (b) (4)<br>(b) (4) | 20 Oct 2020 17:21:04 |

**US3642217**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'I'  | System           | 20 Oct 2020 17:21:04 |



**US3642217**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Was Contact Attempted?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:12:31 |
| User entered 'Yes (Y)'    | Jennifer Morales (b) (4)<br>(b) (4) | 27 Oct 2020 18:10:12 |

**US3642217**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:12:31 |
| User entered '27 Oct 2020' | Jennifer Morales (b) (4)<br>(b) (4) | 27 Oct 2020 18:10:12 |

**US3642217**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded.                  | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                        | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:12:31 |
| User entered 'Contact Made (CONTACT MADE)' | Jennifer Morales (b) (4)<br>(b) (4) | 27 Oct 2020 18:10:12 |

**US3642217**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:12:31 |
| User entered empty.       | Jennifer Morales (b) (4)<br>(b) (4) | 27 Oct 2020 18:10:12 |

**US3642217**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:12:43 |
| User entered 'Yes (Y)'    | Jennifer Morales (b) (4)<br>(b) (4) | 27 Oct 2020 18:10:19 |

**US3642217**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'I'  | System           | 27 Oct 2020 18:10:19 |

**US3642217**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Was Contact Attempted?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:13:00 |
| User entered 'Yes (Y)'    | Jennifer Morales (b) (4)<br>(b) (4) | 04 Nov 2020 17:54:35 |

**US3642217**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:13:00 |
| User entered '04 Nov 2020' | Jennifer Morales (b) (4)<br>(b) (4) | 04 Nov 2020 17:54:35 |



**US3642217**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded.                  | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                        | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:13:00 |
| User entered 'Contact Made (CONTACT MADE)' | Jennifer Morales (b) (4)<br>(b) (4) | 04 Nov 2020 17:54:35 |

US3642217

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:16:22

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 08 Dec 2020 19:13:00 |
| User entered empty.       | Jennifer Morales (b) (4)<br>(b) (4) | 04 Nov 2020 17:54:35 |

**US3642217**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:13:05 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 12 Nov 2020 16:00:44 |

**US3642217**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'I'  | System           | 12 Nov 2020 16:00:44 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:34 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 12 Nov 2020 16:01:06 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:34 |
| User entered '10 Nov 2020' | Son Do (b) (4)              | 12 Nov 2020 16:01:06 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:34 |
| User entered 'Clinic (Clinic)' | Son Do (b) (4)              | 12 Nov 2020 16:01:06 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'VISIT3' | System           | 12 Nov 2020 16:01:06 |



**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:57 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:57 |
| User entered '10 Nov 2020' | Son Do (b) (4)              | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:57 |
| User entered '14:19'      | Son Do (b) (4)              | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered '10 Nov 2020 14:19' | System           | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:57 |
| User entered '98.3' F     | Son Do (b) (4)              | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:57 |
| User entered 'Oral (Oral)' | Son Do (b) (4)              | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:57 |
| User entered empty.       | Son Do (b) (4)              | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:57 |
| User entered '72'         | Son Do (b) (4)              | 12 Nov 2020 16:01:48 |



**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'bpm' | System           | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:57 |
| User entered '14'         | Son Do (b) (4)              | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'breaths/min' | System           | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:57 |
| User entered '127'        | Son Do (b) (4)              | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'mmHg' | System           | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:57 |
| User entered '66'         | Son Do (b) (4)              | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'mmHg' | System           | 12 Nov 2020 16:01:48 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
|                   |                  |                      |



**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
|                   |                  |                      |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:16:22**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:42 |
| User entered 'No (N)'     | Son Do (b) (4)              | 12 Nov 2020 16:01:53 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:16:22**

**Date of examination (dd MMM yyyy)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:14:42 |
| User entered empty.       | Son Do (b) (4)              | 12 Nov 2020 16:01:53 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:15:05 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 12 Nov 2020 16:02:05 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:15:05 |
| User entered '10 Nov 2020' | Son Do (b) (4)              | 12 Nov 2020 16:02:05 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:15:05 |
| User entered '14:43'      | Son Do (b) (4)              | 12 Nov 2020 16:02:05 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered '10 Nov 2020 14:43' | System           | 12 Nov 2020 16:02:05 |

**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Mar 2021 09:39:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:15:15 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 12 Nov 2020 16:02:09 |



**US3642217**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'I'  | System           | 12 Nov 2020 16:02:09 |

**US3642217**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.    | System           | 15 Sep 2020 23:01:12 |
| User entered 'Day 64' | System           | 15 Sep 2020 23:01:12 |

US3642217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-11-17T18:11:30', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fc3d5745-1724-48c6-aa90-f2d40922c457' | System           | 18 Nov 2020 02:11:46 |
| User entered 'No (N)'  | System           | 18 Nov 2020 02:11:46 |

US3642217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:16:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-11-17T18:11:36', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fc3d5745-1724-48c6-aa90-f2d40922c457' | System           | 18 Nov 2020 02:11:46 |
| User entered 'No (N)'  | System           | 18 Nov 2020 02:11:46 |

**US3642217**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-11-17T18:11:43', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'fc3d5745-1724-48c6-aa90-f2d40922c457' | System           | 18 Nov 2020 02:11:46 |
| User entered '17 Nov 2020 18:11:43'  | System           | 18 Nov 2020 02:11:46 |

**US3642217**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.               | System           | 15 Sep 2020 23:01:12 |
| User entered '15 Nov 2020 00:01' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 13:09:40 |
| Data entry locked.               | System           | 15 Sep 2020 23:01:12 |
| User entered '19 Nov 2020 23:59' | System           | 15 Sep 2020 23:01:12 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-11-23T19:11:57', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e7fc5dfa-896e-4f19-acb2-490a5c388126' | System | 24 Nov 2020 03:12:12 |
| User entered 'No (N)'  | System | 24 Nov 2020 03:12:12 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-11-23T19:12:01', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e7fc5dfa-896e-4f19-acb2-490a5c388126' | System | 24 Nov 2020 03:12:12 |
| User entered 'No (N)'  | System | 24 Nov 2020 03:12:12 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-11-23T19:12:08', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e7fc5dfa-896e-4f19-acb2-490a5c388126' | System | 24 Nov 2020 03:12:12 |
| User entered '23 Nov 2020 19:12:08'  | System | 24 Nov 2020 03:12:12 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '19 Nov 2020 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '23 Nov 2020 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '26 Nov 2020 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '30 Nov 2020 23:59' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '03 Dec 2020 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '07 Dec 2020 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-10T10:34:30', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '11697b5d-089f-4fac-8a09-6c0261a4fc44' | System | 10 Dec 2020 18:34:49 |
| User entered 'No (N)'  | System | 10 Dec 2020 18:34:49 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-10T10:34:34', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '11697b5d-089f-4fac-8a09-6c0261a4fc44' | System | 10 Dec 2020 18:34:49 |
| User entered 'No (N)'  | System | 10 Dec 2020 18:34:49 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-10T10:34:43', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '11697b5d-089f-4fac-8a09-6c0261a4fc44' | System | 10 Dec 2020 18:34:49 |
| User entered '10 Dec 2020 10:34:43'  | System | 10 Dec 2020 18:34:49 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '10 Dec 2020 00:01' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '14 Dec 2020 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-17T12:04:24', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '9efadaae-b3de-4173-82ae-cdd719e334f5' | System | 17 Dec 2020 20:04:42 |
| User entered 'No (N)'  | System | 17 Dec 2020 20:04:42 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-17T12:04:28', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '9efadaae-b3de-4173-82ae-cdd719e334f5' | System | 17 Dec 2020 20:04:42 |
| User entered 'No (N)'  | System | 17 Dec 2020 20:04:42 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-17T12:04:36', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '9efadaae-b3de-4173-82ae-cdd719e334f5' | System | 17 Dec 2020 20:04:42 |
| User entered '17 Dec 2020 12:04:36'  | System | 17 Dec 2020 20:04:42 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '17 Dec 2020 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '21 Dec 2020 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-24T14:23:14', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '69380450-5720-4f4f-812f-245980d0689d' | System | 24 Dec 2020 22:24:05 |
| User entered 'Yes (Y)'   | System | 24 Dec 2020 22:24:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-24T14:23:20', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '69380450-5720-4f4f-812f-245980d0689d' | System | 24 Dec 2020 22:24:05 |
| User entered 'No (N)'  | System | 24 Dec 2020 22:24:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-24T14:23:24', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '69380450-5720-4f4f-812f-245980d0689d' | System | 24 Dec 2020 22:24:05 |
| User entered 'No (N)'  | System | 24 Dec 2020 22:24:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-24T14:23:36', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '69380450-5720-4f4f-812f-245980d0689d' | System | 24 Dec 2020 22:24:05 |
| User entered 'Yes (Y)'   | System | 24 Dec 2020 22:24:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-24T14:23:49', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '69380450-5720-4f4f-812f-245980d0689d' | System | 24 Dec 2020 22:24:05 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 24 Dec 2020 22:24:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-24T14:23:54', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '69380450-5720-4f4f-812f-245980d0689d' User entered '24 Dec 2020 14:23:54' | System | 24 Dec 2020 22:24:05 |
|  | System | 24 Dec 2020 22:24:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '24 Dec 2020 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '28 Dec 2020 23:59' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-31T18:15:05', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '757aa2a5-bf35-4d3d-ba7d-80c89fbffe8' | System | 01 Jan 2021 02:15:48 |
| User entered 'No (N)'   | System | 01 Jan 2021 02:15:48 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-31T18:15:19', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '757aa2a5-bf35-4d3d-ba7d-80c89fbffe8' | System | 01 Jan 2021 02:15:48 |
| User entered 'No (N)'   | System | 01 Jan 2021 02:15:48 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2020-12-31T18:15:40', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '757aa2a5-bf35-4d3d-ba7d-80c89fbffe8' | System | 01 Jan 2021 02:15:48 |
| User entered '31 Dec 2020 18:15:40'   | System | 01 Jan 2021 02:15:48 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '31 Dec 2020 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '04 Jan 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-07T17:55:13', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'd636a77d-44e9-4e28-bb4a-7d82abc5d756' | System | 08 Jan 2021 01:55:33 |
| User entered 'No (N)'  | System | 08 Jan 2021 01:55:33 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-07T17:55:16', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'd636a77d-44e9-4e28-bb4a-7d82abc5d756' | System | 08 Jan 2021 01:55:33 |
| User entered 'No (N)'  | System | 08 Jan 2021 01:55:33 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-07T17:55:26', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'd636a77d-44e9-4e28-bb4a-7d82abc5d756' | System | 08 Jan 2021 01:55:33 |
| User entered '07 Jan 2021 17:55:26'  | System | 08 Jan 2021 01:55:33 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '07 Jan 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '11 Jan 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-14T10:13:06', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8a22f14-fa14-43f5-a4fe-d6d878b4300f' | System | 14 Jan 2021 18:14:15 |
| User entered 'Yes (Y)'   | System | 14 Jan 2021 18:14:15 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-14T10:13:09', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8a22f14-fa14-43f5-a4fe-d6d878b4300f' | System | 14 Jan 2021 18:14:15 |
| User entered 'No (N)'  | System | 14 Jan 2021 18:14:15 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-14T10:13:12', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8a22f14-fa14-43f5-a4fe-d6d878b4300f' | System | 14 Jan 2021 18:14:15 |
| User entered 'No (N)'  | System | 14 Jan 2021 18:14:15 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-14T10:13:36', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8a22f14-fa14-43f5-a4fe-d6d878b4300f' | System | 14 Jan 2021 18:14:15 |
| User entered 'Yes (Y)'   | System | 14 Jan 2021 18:14:15 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-14T10:13:52', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8a22f14-fa14-43f5-a4fe-d6d878b4300f' | System | 14 Jan 2021 18:14:15 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 14 Jan 2021 18:14:15 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-14T10:14:04', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'b8a22f14-fa14-43f5-a4fe-d6d878b4300f' User entered '14 Jan 2021 10:14:04' | System | 14 Jan 2021 18:14:15 |
|  | System | 14 Jan 2021 18:14:15 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '14 Jan 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '18 Jan 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-21T09:08:34', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '67f7eea1-da99-4b1a-bd84-1469cf67a879' | System | 21 Jan 2021 17:08:50 |
| User entered 'No (N)'  | System | 21 Jan 2021 17:08:50 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-21T09:08:37', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '67f7eea1-da99-4b1a-bd84-1469cf67a879' | System | 21 Jan 2021 17:08:50 |
| User entered 'No (N)'  | System | 21 Jan 2021 17:08:50 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-21T09:08:47', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '67f7eea1-da99-4b1a-bd84-1469cf67a879' | System | 21 Jan 2021 17:08:50 |
| User entered '21 Jan 2021 09:08:47'  | System | 21 Jan 2021 17:08:50 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '21 Jan 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '25 Jan 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-30T04:29:51', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '4ec7bdd7-2b56-4db7-9781-d95a40a0e89b' | System | 30 Jan 2021 12:30:05 |
| User entered 'No (N)'  | System | 30 Jan 2021 12:30:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-30T04:29:54', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '4ec7bdd7-2b56-4db7-9781-d95a40a0e89b' | System | 30 Jan 2021 12:30:05 |
| User entered 'No (N)'  | System | 30 Jan 2021 12:30:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-01-30T04:30:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '4ec7bdd7-2b56-4db7-9781-d95a40a0e89b' | System | 30 Jan 2021 12:30:05 |
| User entered '30 Jan 2021 04:30:00'  | System | 30 Jan 2021 12:30:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '28 Jan 2021 00:01' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '01 Feb 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-04T18:19:25', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e24ba5d7-b0bc-40f8-a50f-34c6bfccb27e' | System | 05 Feb 2021 02:20:39 |
| User entered 'Yes (Y)'   | System | 05 Feb 2021 02:20:39 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-04T18:19:28', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e24ba5d7-b0bc-40f8-a50f-34c6bfccb27e' | System | 05 Feb 2021 02:20:39 |
| User entered 'No (N)'  | System | 05 Feb 2021 02:20:39 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-04T18:19:31', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e24ba5d7-b0bc-40f8-a50f-34c6bfccb27e' | System | 05 Feb 2021 02:20:39 |
| User entered 'No (N)'  | System | 05 Feb 2021 02:20:39 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-04T18:19:36', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e24ba5d7-b0bc-40f8-a50f-34c6bfccb27e' | System | 05 Feb 2021 02:20:39 |
| User entered 'Yes (Y)'   | System | 05 Feb 2021 02:20:39 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-04T18:19:45', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e24ba5d7-b0bc-40f8-a50f-34c6bfccb27e' | System | 05 Feb 2021 02:20:39 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 05 Feb 2021 02:20:39 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-04T18:19:54', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e24ba5d7-b0bc-40f8-a50f-34c6bfccb27e' | System | 05 Feb 2021 02:20:39 |
| User entered '04 Feb 2021 18:19:54'  | System | 05 Feb 2021 02:20:39 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '04 Feb 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '08 Feb 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-11T13:43:18', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '65452682-bc14-4b95-a288-7786d3ff5534' | System | 11 Feb 2021 21:43:35 |
| User entered 'No (N)'  | System | 11 Feb 2021 21:43:35 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-11T13:43:21', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '65452682-bc14-4b95-a288-7786d3ff5534' | System | 11 Feb 2021 21:43:35 |
| User entered 'No (N)'  | System | 11 Feb 2021 21:43:35 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-11T13:43:26', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '65452682-bc14-4b95-a288-7786d3ff5534' User entered '11 Feb 2021 13:43:26' | System | 11 Feb 2021 21:43:35 |
|  | System | 11 Feb 2021 21:43:35 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '11 Feb 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '15 Feb 2021 23:59' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-18T12:42:17', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '90c1db5d-77db-4fdb-a6cd-8bddc3007f4f' | System | 18 Feb 2021 20:43:05 |
| User entered 'Yes (Y)'   | System | 18 Feb 2021 20:43:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-18T12:42:21', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '90c1db5d-77db-4fdb-a6cd-8bddc3007f4f' | System | 18 Feb 2021 20:43:05 |
| User entered 'No (N)'  | System | 18 Feb 2021 20:43:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-18T12:42:25', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '90c1db5d-77db-4fdb-a6cd-8bddc3007f4f' | System | 18 Feb 2021 20:43:05 |
| User entered 'No (N)'  | System | 18 Feb 2021 20:43:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-18T12:42:38', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '90c1db5d-77db-4fdb-a6cd-8bddc3007f4f' | System | 18 Feb 2021 20:43:05 |
| User entered 'Yes (Y)'   | System | 18 Feb 2021 20:43:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-18T12:42:46', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '90c1db5d-77db-4fdb-a6cd-8bddc3007f4f' | System | 18 Feb 2021 20:43:05 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 18 Feb 2021 20:43:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-18T12:42:53', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '90c1db5d-77db-4fdb-a6cd-8bddc3007f4f' User entered '18 Feb 2021 12:42:53' | System | 18 Feb 2021 20:43:05 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '18 Feb 2021 00:01' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '22 Feb 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-27T09:28:56-08:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c4c88b89-298c-4a9b-b69c-31c186c5d17c' User entered 'No (N)' | System | 27 Feb 2021 17:29:15 |
|  | System | 27 Feb 2021 17:29:15 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-27T09:29:01-08:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c4c88b89-298c-4a9b-b69c-31c186c5d17c' User entered 'No (N)' | System | 27 Feb 2021 17:29:15 |
|  | System | 27 Feb 2021 17:29:15 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-02-27T09:29:12-08:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'c4c88b89-298c-4a9b-b69c-31c186c5d17c' User entered '27 Feb 2021 09:29:12' | System | 27 Feb 2021 17:29:15 |
|  | System | 27 Feb 2021 17:29:15 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '25 Feb 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '01 Mar 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-04T23:58:16-08:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '7c4b5b1e-2820-43f7-8060-0930d736e0ea' User entered 'No (N)' | System | 05 Mar 2021 07:58:31 |
|  | System | 05 Mar 2021 07:58:31 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-04T23:58:19-08:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '7c4b5b1e-2820-43f7-8060-0930d736e0ea' | System | 05 Mar 2021 07:58:31 |
| User entered 'No (N)'  | System | 05 Mar 2021 07:58:31 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-04T23:58:27-08:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '7c4b5b1e-2820-43f7-8060-0930d736e0ea' User entered '04 Mar 2021 23:58:27' | System | 05 Mar 2021 07:58:31 |
|  | System | 05 Mar 2021 07:58:31 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '04 Mar 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '08 Mar 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-11T13:33:01-08:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3a2f959d-ec6e-4c0e-85df-a412af58ce4b' | System | 11 Mar 2021 21:33:26 |
| User entered 'No (N)'  | System | 11 Mar 2021 21:33:26 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-11T13:33:07-08:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3a2f959d-ec6e-4c0e-85df-a412af58ce4b' | System | 11 Mar 2021 21:33:26 |
| User entered 'No (N)'  | System | 11 Mar 2021 21:33:26 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-11T13:33:17-08:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '3a2f959d-ec6e-4c0e-85df-a412af58ce4b' User entered '11 Mar 2021 13:33:17' | System | 11 Mar 2021 21:33:26 |
|  | System | 11 Mar 2021 21:33:26 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '11 Mar 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '15 Mar 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-19T10:34:44-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e9684654-5444-4b08-965b-d87cd56094a3' | System | 19 Mar 2021 17:34:55 |
| User entered 'No (N)'  | System | 19 Mar 2021 17:34:55 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-19T10:34:47-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e9684654-5444-4b08-965b-d87cd56094a3' | System | 19 Mar 2021 17:34:55 |
| User entered 'No (N)'  | System | 19 Mar 2021 17:34:55 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-19T10:34:50-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: 'e9684654-5444-4b08-965b-d87cd56094a3' | System | 19 Mar 2021 17:34:55 |
| User entered '19 Mar 2021 10:34:50'  | System | 19 Mar 2021 17:34:55 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '18 Mar 2021 00:01' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '22 Mar 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-25T23:18:44-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '5598addf-2d42-4927-8f2f-ce9014d66c60' | System | 26 Mar 2021 06:18:55 |
| User entered 'No (N)'  | System | 26 Mar 2021 06:18:55 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-25T23:18:47-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '5598addf-2d42-4927-8f2f-ce9014d66c60' | System | 26 Mar 2021 06:18:55 |
| User entered 'No (N)'  | System | 26 Mar 2021 06:18:55 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-25T23:18:51-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '5598addf-2d42-4927-8f2f-ce9014d66c60' | System | 26 Mar 2021 06:18:55 |
| User entered '25 Mar 2021 23:18:51'  | System | 26 Mar 2021 06:18:55 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '25 Mar 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '29 Mar 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-04-01T08:26:43-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '87f97e05-feaf-426c-8482-fa57cad93abc' | System | 01 Apr 2021 15:26:53 |
| User entered 'No (N)'  | System | 01 Apr 2021 15:26:53 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-04-01T08:26:46-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '87f97e05-feaf-426c-8482-fa57cad93abc' | System | 01 Apr 2021 15:26:53 |
| User entered 'No (N)'  | System | 01 Apr 2021 15:26:53 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-04-01T08:26:50-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '87f97e05-feaf-426c-8482-fa57cad93abc' | System | 01 Apr 2021 15:26:53 |
| User entered '01 Apr 2021 08:26:50'  | System | 01 Apr 2021 15:26:53 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '01 Apr 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '05 Apr 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-04-09T10:37:15-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '5f1a8a1a-fdcb-48d1-be5f-52efad075a1c' | System | 09 Apr 2021 17:37:26 |
| User entered 'No (N)'  | System | 09 Apr 2021 17:37:26 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-04-09T10:37:18-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '5f1a8a1a-fdcb-48d1-be5f-52efad075a1c' | System | 09 Apr 2021 17:37:26 |
| User entered 'No (N)'  | System | 09 Apr 2021 17:37:26 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-04-09T10:37:22-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '5f1a8a1a-fdcb-48d1-be5f-52efad075a1c' User entered '09 Apr 2021 10:37:22' | System | 09 Apr 2021 17:37:26 |
|  | System | 09 Apr 2021 17:37:26 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '08 Apr 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '12 Apr 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-04-15T14:43:26-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '81550250-9bbb-44ae-b50f-574f485598d2' | System | 15 Apr 2021 21:43:38 |
| User entered 'No (N)'  | System | 15 Apr 2021 21:43:38 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-04-15T14:43:29-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '81550250-9bbb-44ae-b50f-574f485598d2' | System | 15 Apr 2021 21:43:38 |
| User entered 'No (N)'  | System | 15 Apr 2021 21:43:38 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-04-15T14:43:32-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '81550250-9bbb-44ae-b50f-574f485598d2' | System | 15 Apr 2021 21:43:38 |
| User entered '15 Apr 2021 14:43:32'  | System | 15 Apr 2021 21:43:38 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '15 Apr 2021 00:01' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '19 Apr 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '22 Apr 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '26 Apr 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-04-29T13:20:35-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '24e70e52-8a68-4b2b-a1a3-a8108a91dc47' | System | 29 Apr 2021 20:20:51 |
| User entered 'No (N)'  | System | 29 Apr 2021 20:20:51 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-04-29T13:20:38-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '24e70e52-8a68-4b2b-a1a3-a8108a91dc47' | System | 29 Apr 2021 20:20:51 |
| User entered 'No (N)'  | System | 29 Apr 2021 20:20:51 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-04-29T13:20:46-07:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '24e70e52-8a68-4b2b-a1a3-a8108a91dc47' | System | 29 Apr 2021 20:20:51 |
| User entered '29 Apr 2021 13:20:46'  | System | 29 Apr 2021 20:20:51 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '29 Apr 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '03 May 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '06 May 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '10 May 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '13 May 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '17 May 2021 23:59' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '20 May 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '24 May 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '27 May 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '31 May 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '03 Jun 2021 00:01' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '07 Jun 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '10 Jun 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '14 Jun 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '17 Jun 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '21 Jun 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '24 Jun 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '28 Jun 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '01 Jul 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '05 Jul 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '08 Jul 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '12 Jul 2021 23:59' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '15 Jul 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '19 Jul 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '22 Jul 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '26 Jul 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '29 Jul 2021 00:01' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '02 Aug 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '05 Aug 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '09 Aug 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '12 Aug 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '16 Aug 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '19 Aug 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '23 Aug 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '26 Aug 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '30 Aug 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '02 Sep 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '06 Sep 2021 23:59' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '09 Sep 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '13 Sep 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '16 Sep 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '20 Sep 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '23 Sep 2021 00:01' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '27 Sep 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '30 Sep 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '04 Oct 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '07 Oct 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '11 Oct 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '14 Oct 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '18 Oct 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '21 Oct 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '25 Oct 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '28 Oct 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '01 Nov 2021 23:59' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '04 Nov 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '08 Nov 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '11 Nov 2021 00:01' | System | 20 Nov 2020 08:48:57 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '15 Nov 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '18 Nov 2021 00:01' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '22 Nov 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 08:48:57 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '25 Nov 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '29 Nov 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '02 Dec 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '06 Dec 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '09 Dec 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '13 Dec 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '16 Dec 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '20 Dec 2021 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '23 Dec 2021 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '27 Dec 2021 23:59' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '30 Dec 2021 00:01' | System | 20 Nov 2020 08:48:57 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '03 Jan 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '06 Jan 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '10 Jan 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '13 Jan 2022 00:01' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '17 Jan 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '20 Jan 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '24 Jan 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '27 Jan 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '31 Jan 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 08:48:57 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '03 Feb 2022 00:01' | System | 20 Nov 2020 08:48:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '07 Feb 2022 23:59' | System | 20 Nov 2020 08:48:57 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 08:48:57 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '10 Feb 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '14 Feb 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '17 Feb 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '21 Feb 2022 23:59' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '24 Feb 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '28 Feb 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '03 Mar 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '07 Mar 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '10 Mar 2022 00:01' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '14 Mar 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '17 Mar 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '21 Mar 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '24 Mar 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '28 Mar 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '31 Mar 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '04 Apr 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '07 Apr 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '11 Apr 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '14 Apr 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '18 Apr 2022 23:59' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '21 Apr 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '25 Apr 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '28 Apr 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '02 May 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '05 May 2022 00:01' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '09 May 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '12 May 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '16 May 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '19 May 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '23 May 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '26 May 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '30 May 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '02 Jun 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '06 Jun 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '09 Jun 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '13 Jun 2022 23:59' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '16 Jun 2022 00:01' | System | 20 Nov 2020 08:48:57 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '20 Jun 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '23 Jun 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '27 Jun 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '30 Jun 2022 00:01' | System | 20 Nov 2020 08:48:57 |



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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '04 Jul 2022 23:59' | System | 20 Nov 2020 08:48:57 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 08:48:57 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '07 Jul 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '11 Jul 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '14 Jul 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '18 Jul 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '21 Jul 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '25 Jul 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '28 Jul 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '01 Aug 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '04 Aug 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '08 Aug 2022 23:59' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '11 Aug 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '15 Aug 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '18 Aug 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '22 Aug 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '25 Aug 2022 00:01' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '29 Aug 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '01 Sep 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '05 Sep 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '08 Sep 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '12 Sep 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '15 Sep 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '19 Sep 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '22 Sep 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '26 Sep 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '29 Sep 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '03 Oct 2022 23:59' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '06 Oct 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '10 Oct 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '13 Oct 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '17 Oct 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '20 Oct 2022 00:01' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '24 Oct 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '27 Oct 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '31 Oct 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '03 Nov 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '07 Nov 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 08:48:57 |



**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '10 Nov 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '14 Nov 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '17 Nov 2022 00:01' | System | 20 Nov 2020 08:48:57 |

**US3642217**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:16:22**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 08:48:57 |
| Amendment Manager: User entered '21 Nov 2022 23:59' | System | 20 Nov 2020 08:48:57 |

**US3642217****Folder: Cosmetic Injections and Dermal Fillers****Form: Cosmetic Injection\_ Dermal Filler eDiary (1)****Generated On: 10 Jun 2021 09:16:22**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 30 Apr 2021 20:34:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-04T23:58:37-08:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '8b3b0f77-e157-4b56-937d-63b0b284c8ae' | System           | 05 Mar 2021 07:59:06 |
| User entered 'Yes (Y)'   | System           | 05 Mar 2021 07:59:06 |

US3642217

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:16:22**

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 30 Apr 2021 20:34:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-04T23:58:46-08:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '8b3b0f77-e157-4b56-937d-63b0b284c8ae' | System           | 05 Mar 2021 07:59:06 |
| User entered 'No (N)'  | System           | 05 Mar 2021 07:59:06 |

**US3642217**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Date & Time of Submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 30 Apr 2021 20:34:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d40d3214c41943c3)', Time: '2021-03-04T23:58:55-08:00', User OID: 'PatientReportedOutcome (US3642217)', ODM File OID: '8b3b0f77-e157-4b56-937d-63b0b284c8ae' | System           | 05 Mar 2021 07:59:06 |
| User entered '04 Mar 2021 23:58:55'  | System           | 05 Mar 2021 07:59:06 |



**US3642217**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Was Contact Attempted?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| DataPoint Verified.       |                                     | 25 Feb 2021 21:34:43 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lindsey Woronicz (b) (4) | 09 Dec 2020 23:23:39 |

**US3642217**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| DataPoint Verified.       |                                     | 25 Feb 2021 21:34:43 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered '9 Dec 2020' | (b) (4)<br>Lindsey Woronicz (b) (4) | 09 Dec 2020 23:23:39 |

**US3642217**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| DataPoint Verified.                        |                                     | 25 Feb 2021 21:34:43 |
| User signature succeeded.                  | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Lindsey Woronicz (b) (4) | 09 Dec 2020 23:23:39 |

US3642217

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:16:22

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| DataPoint Verified.       |                                     | 25 Feb 2021 21:34:43 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Lindsey Woronicz (b) (4) | 09 Dec 2020 23:23:39 |

US3642217

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:16:22

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 27 Mar 2021 09:39:53 |
| DataPoint Verified.       |                                     | 25 Feb 2021 21:34:50 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lindsey Woronicz (b) (4) | 09 Dec 2020 23:23:44 |

**US3642217**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 09:39:53 |
| User entered 'I'  | System           | 09 Dec 2020 23:23:44 |

**US3642217**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Was Contact Attempted?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 14 Apr 2021 09:18:56 |
| DataPoint Verified.       |                          | 25 Feb 2021 21:34:01 |
| User signature succeeded. | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Lindsey Woronicz (b) (4) | 12 Jan 2021 19:56:09 |
|                           |                          |                      |

**US3642217**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 14 Apr 2021 09:18:56 |
| DataPoint Verified.        |                                     | 25 Feb 2021 21:34:01 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered '12 Jan 2021' | (b) (4)<br>Lindsey Woronicz (b) (4) | 12 Jan 2021 19:56:09 |



**US3642217**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                    | 14 Apr 2021 09:18:56 |
| DataPoint Verified.                        |                                     | 25 Feb 2021 21:34:01 |
| User signature succeeded.                  | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Lindsey Woronicz (b) (4) | 12 Jan 2021 19:56:09 |

US3642217

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:16:22

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 14 Apr 2021 09:18:56 |
| DataPoint Verified.       |                                     | 25 Feb 2021 21:34:01 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Lindsey Woronicz (b) (4) | 12 Jan 2021 19:56:09 |

US3642217

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:16:22

[Is the participant continuing to the next visit?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 14 Apr 2021 09:18:56 |
| DataPoint Verified.       |                          | 25 Feb 2021 21:34:57 |
| User signature succeeded. | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Lindsey Woronicz (b) (4) | 12 Jan 2021 19:58:28 |
|                           |                          |                      |

**US3642217**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 09:18:56 |
| User entered 'I'  | System           | 12 Jan 2021 19:58:28 |

**US3642217**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Was Contact Attempted?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 14 Apr 2021 09:18:56 |
| DataPoint Verified.       |  | 25 Feb 2021 21:35:45 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Morales (b) (4)<br>(b) (4) | 10 Feb 2021 18:32:05 |

**US3642217**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 14 Apr 2021 09:18:56 |
| DataPoint Verified.        | (b) (4)  | 25 Feb 2021 21:35:45 |
| User signature succeeded.  | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered '10 Feb 2021' | (b) (4)<br>Jennifer Morales (b) (4)<br>(b) (4) | 10 Feb 2021 18:32:05 |

**US3642217**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Please select one status for the follow-up contact](#)

| Audit                                      | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                               | 14 Apr 2021 09:18:56 |
| DataPoint Verified.                        |  | 25 Feb 2021 21:35:45 |
| User signature succeeded.                  | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Jennifer Morales (b) (4)<br>(b) (4) | 10 Feb 2021 18:32:05 |

**US3642217**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 14 Apr 2021 09:18:56 |
| DataPoint Verified.       | (b) (4)  | 25 Feb 2021 21:35:45 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Jennifer Morales (b) (4)<br>(b) (4) | 10 Feb 2021 18:32:05 |



US3642217

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:16:22

[Is the participant continuing to the next visit?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 14 Apr 2021 09:18:56 |
| DataPoint Verified.       |  | 25 Feb 2021 21:35:49 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Morales (b) (4)<br>(b) (4) | 10 Feb 2021 18:32:12 |

**US3642217**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 09:18:56 |
| User entered 'I'  | System           | 10 Feb 2021 18:32:12 |

**US3642217**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Was Contact Attempted?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 13:07:05 |
| DataPoint Verified.       |  | 07 Apr 2021 21:35:43 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Mar 2021 02:20:57 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Morales (b) (4)<br>(b) (4) | 09 Mar 2021 18:21:25 |

**US3642217**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 30 Apr 2021 13:07:05 |
| DataPoint Verified.        |  | 07 Apr 2021 21:35:43 |
| User signature succeeded.  | Stephen Spector (b) (4)                        | 13 Mar 2021 02:20:57 |
| User entered '09 Mar 2021' | (b) (4)<br>Jennifer Morales (b) (4)<br>(b) (4) | 09 Mar 2021 18:21:25 |

**US3642217**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:16:22**

[Please select one status for the follow-up contact](#)

| Audit                                      | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                               | 30 Apr 2021 13:07:05 |
| DataPoint Verified.                        |  | 07 Apr 2021 21:35:43 |
| User signature succeeded.                  | Stephen Spector (b) (4)                        | 13 Mar 2021 02:20:57 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Jennifer Morales (b) (4)<br>(b) (4) | 09 Mar 2021 18:21:25 |

US3642217

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:16:22

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 30 Apr 2021 13:07:05 |
| DataPoint Verified.       |                                     | 07 Apr 2021 21:35:43 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Mar 2021 02:20:57 |
| User entered empty.       | (b) (4)<br>Jennifer Morales (b) (4) | 09 Mar 2021 18:21:25 |
|                           | (b) (4)                             |                      |

US3642217

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:16:22

[Is the participant continuing to the next visit?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 13:07:05 |
| DataPoint Verified.       |  | 07 Apr 2021 21:35:51 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Mar 2021 02:20:57 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Morales (b) (4)<br>(b) (4) | 09 Mar 2021 18:21:31 |

**US3642217**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:07:05 |
| User entered 'I'  | System           | 09 Mar 2021 18:21:31 |



**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Was this visit performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:07 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered 'Yes (Y)'    | Son Do (b) (4)          | 15 Apr 2021 14:52:02 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 20 Apr 2021 15:23:07 |
| User signature succeeded.  | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered '12 Apr 2021' | Son Do (b) (4)          | 15 Apr 2021 14:52:02 |

US3642217

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:16:22

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)        | 20 Apr 2021 15:23:07 |
| User signature succeeded.      | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered 'Clinic (Clinic)' | Son Do (b) (4)          | 15 Apr 2021 14:52:02 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT4' | System | 15 Apr 2021 14:52:02 |

US3642217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[Were vital signs assessed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:09 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered 'No (N)'     | Son Do (b) (4)          | 15 Apr 2021 14:52:09 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:09 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered empty.       | Son Do (b) (4)          | 15 Apr 2021 14:52:09 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

**Time of assessment (00:00-23:59)**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:09 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered empty.       | Son Do (b) (4)          | 15 Apr 2021 14:52:09 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Apr 2021 14:52:09 |



US3642217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

Temperature (xxx.x)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:09 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered empty.       | Son Do (b) (4)          | 15 Apr 2021 14:52:09 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Route of measurement](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:09 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered empty.       | Son Do (b) (4)          | 15 Apr 2021 14:52:09 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[If Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:09 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered empty.       | Son Do (b) (4)          | 15 Apr 2021 14:52:09 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Pulse \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:09 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered empty.       | Son Do (b) (4)          | 15 Apr 2021 14:52:09 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Apr 2021 14:52:09 |

US3642217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:09 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered empty.       | Son Do (b) (4)          | 15 Apr 2021 14:52:09 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Respiratory Rate units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Apr 2021 14:52:09 |

US3642217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

Systolic Blood Pressure (xxx)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:09 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered empty.       | Son Do (b) (4)          | 15 Apr 2021 14:52:09 |



**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Apr 2021 14:52:09 |

US3642217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:16:22

Diastolic Blood Pressure (xxx)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:09 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered empty.       | Son Do (b) (4)          | 15 Apr 2021 14:52:09 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:16:22**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Apr 2021 14:52:09 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:16:22**

[Was the physical examination performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:02 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered 'No (N)'     | Son Do (b) (4)          | 15 Apr 2021 14:52:15 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:16:22**

**Date of examination (dd MMM yyyy)**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:23:02 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered empty.       | Son Do (b) (4)          | 15 Apr 2021 14:52:15 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Was the sample collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:22:55 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered 'Yes (Y)'    | Son Do (b) (4)          | 15 Apr 2021 14:52:27 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 20 Apr 2021 15:22:55 |
| User signature succeeded.  | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered '12 Apr 2021' | Son Do (b) (4)          | 15 Apr 2021 14:52:27 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

**Collection time (00:00-23:59)**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:22:55 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered '14:19'      | Son Do (b) (4)          | 15 Apr 2021 14:52:27 |



**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Apr 2021 14:19' | System | 15 Apr 2021 14:52:27 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:22:51 |
| User signature succeeded. | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered 'Yes (Y)'    | Son Do (b) (4)          | 15 Apr 2021 14:52:32 |

**US3642217**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Apr 2021 14:52:32 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Was this visit performed?](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 28 Apr 2021 19:15:39 |
| DataPoint Verified.       |                           | 25 Feb 2021 21:36:14 |
| User signature succeeded. | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'    | (b) (4)<br>Son Do (b) (4) | 25 Jan 2021 18:23:47 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                      | Time (GMT)           |
|----------------------------|---------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)          | 28 Apr 2021 19:15:39 |
| DataPoint Verified.        |                           | 25 Feb 2021 21:36:14 |
| User signature succeeded.  | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered '21 Jan 2021' | (b) (4)<br>Son Do (b) (4) | 25 Jan 2021 18:23:47 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                      | Time (GMT)           |
|--------------------------------|---------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)          | 28 Apr 2021 19:15:39 |
| DataPoint Verified.            |                           | 25 Feb 2021 21:36:14 |
| User signature succeeded.      | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Son Do (b) (4) | 25 Jan 2021 18:23:47 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:16:22**

[Folder OID](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 19:15:39 |
| User entered 'UNBLND_DECIDE' | System           | 25 Jan 2021 18:23:47 |

US3642217

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:16:22

Date of updated informed consent (*dd MMM yyyy*)

| Audit                      | User                      | Time (GMT)           |
|----------------------------|---------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)          | 28 Apr 2021 19:15:39 |
| DataPoint Verified.        |                           | 25 Feb 2021 21:36:32 |
| User signature succeeded.  | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered '21 Jan 2021' | (b) (4)<br>Son Do (b) (4) | 25 Jan 2021 18:24:06 |



**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:16:22**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)        | 28 Apr 2021 19:15:39 |
| User signature succeeded.                  | Stephen Spector (b) (4) | 13 Mar 2021 02:20:57 |
| User entered '0' WR# 5295537               | (b) (4)                 | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System                  | 06 Mar 2021 19:29:35 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:16:22**

[Was the participant unblinded?](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 28 Apr 2021 19:15:39 |
| DataPoint Verified.       |                           | 25 Feb 2021 21:36:32 |
| User signature succeeded. | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'    | (b) (4)<br>Son Do (b) (4) | 25 Jan 2021 18:24:06 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:16:22**

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 28 Apr 2021 19:15:39 |
| User signature succeeded.   | Stephen Spector (b) (4) | 13 Mar 2021 02:20:57 |
| User entered 'AMENDMENT 6 OR LATER<br>(AMENDMENT 6 OR LATER)' WR# 5295537 | (b) (4)<br>System       | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint.                                | System                  | 06 Mar 2021 19:29:35 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:16:22**

[Date of unblinding \(dd MMM yyyy\)](#)

| Audit                      | User                      | Time (GMT)           |
|----------------------------|---------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)          | 28 Apr 2021 19:15:39 |
| DataPoint Verified.        |                           | 25 Feb 2021 21:36:32 |
| User signature succeeded.  | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered '21 Jan 2021' | (b) (4)<br>Son Do (b) (4) | 25 Jan 2021 18:24:06 |

US3642217

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:16:22

[Participant randomization assignment](#)

| Audit                                | User                      | Time (GMT)           |
|--------------------------------------|---------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)          | 28 Apr 2021 19:15:39 |
| DataPoint Verified.                  |                           | 25 Feb 2021 21:36:32 |
| User signature succeeded.            | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4)<br>Son Do (b) (4) | 25 Jan 2021 18:24:06 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:16:22**

[Actual Dose 1](#)

| Audit                                | User                      | Time (GMT)           |
|--------------------------------------|---------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)          | 28 Apr 2021 19:15:39 |
| DataPoint Verified.                  |                           | 25 Feb 2021 21:36:32 |
| User signature succeeded.            | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4)<br>Son Do (b) (4) | 25 Jan 2021 18:24:06 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:16:22**

[Actual Dose 2](#)

| Audit                                | User                      | Time (GMT)           |
|--------------------------------------|---------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)          | 28 Apr 2021 19:15:39 |
| DataPoint Verified.                  |                           | 25 Feb 2021 21:36:32 |
| User signature succeeded.            | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4)<br>Son Do (b) (4) | 25 Jan 2021 18:24:06 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:16:22**

[Will participant receive mRNA-1273?](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 28 Apr 2021 19:15:39 |
| DataPoint Verified.       |                           | 25 Feb 2021 21:36:32 |
| User signature succeeded. | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | (b) (4)<br>Son Do (b) (4) | 25 Jan 2021 18:24:06 |



**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:16:22**

[Placebo Only Flag](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 19:15:39 |
| User entered empty. | System           | 25 Jan 2021 18:24:06 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:16:22**

[Continuing with mRNA-1273](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 19:15:39 |
| User entered empty. | System           | 25 Jan 2021 18:24:06 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 19:15:39 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:37:09 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 25 Jan 2021 18:24:16 |

US3642217

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:16:22

Collection date (dd MMM yyyy)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 28 Apr 2021 19:15:39 |
| User signature succeeded.   | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 30DEC2020, however this date is presently recorded for the Participant Decision Visit. Please confirm if the Unscheduled sample collected on 21Jan2021 is actually for the Participant Decision Visit in the query response and update if appropriate.' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)         | 01 Mar 2021 19:52:56 |
| DataPoint Verified.   | (b) (4), (b) (6)                    | 25 Feb 2021 21:37:09 |
| Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 30DEC2020, however this date is presently recorded for the Participant Decision Visit. Please confirm if the Unscheduled sample collected on 21Jan2021 is actually for the Participant Decision Visit in the query response and update if appropriate.' answered with 'samples collected on 21JAN2021 were for OL-D1. Will reconcile with PPD central lab data.' (Site from DM). | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:22:20 |
| User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 30DEC2020, however this date is presently recorded for the Participant Decision Visit. Please confirm if the Unscheduled sample collected on 21Jan2021 is actually for the Participant Decision Visit in the query response and update if appropriate.' (Site from DM).  | (b) (4), (b) (6)                    | 04 Feb 2021 16:27:01 |
| User entered '21 Jan 2021'  | Son Do (b) (4)                      | 25 Jan 2021 18:24:16 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 19:15:39 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:37:07 |
| User entered '16:02'      | Son Do (b) (4)              | 25 Jan 2021 18:24:16 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:16:22**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 19:15:39 |
| User entered '21 Jan 2021 16:02' | System           | 25 Jan 2021 18:24:16 |

US3642217

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:16:22

[Was the sample collected?](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 28 Apr 2021 19:15:39 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is an Unscheduled Swab sample collected on 21JAN2021, however, the 21JAN2021 sample is recorded here for the Participant Decision Visit / OL-D1. Please confirm the correct Visit Name in the query response box and be sure to reconcile the PPD portal, as appropriate. ' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 09:31:47 |
| DataPoint Verified.  | (b) (4), (b) (6)                    | 25 Feb 2021 21:37:24 |
| Query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is an Unscheduled Swab sample collected on 21JAN2021, however, the 21JAN2021 sample is recorded here for the Participant Decision Visit / OL-D1. Please confirm the correct Visit Name in the query response box and be sure to reconcile the PPD portal, as appropriate. ' answered with 'correct visit name: OL-D1. Will reconcile with PPD central lab queries. ' (Site from DM). | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:21:25 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is an Unscheduled Swab sample collected on 21JAN2021, however, the 21JAN2021 sample is recorded here for the Participant Decision Visit / OL-D1. Please confirm the correct Visit Name in the query response box and be sure to reconcile the PPD portal, as appropriate. ' (Site from DM).  | (b) (4), (b) (6)                    | 09 Feb 2021 19:44:50 |
| User entered 'Yes (Y)'   | Son Do (b) (4)                      | 25 Jan 2021 18:24:28 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:16:22**

[Collection date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 19:15:39 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:37:24 |
| User entered '21 Jan 2021' | Son Do (b) (4)              | 25 Jan 2021 18:24:28 |



**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:16:22**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 19:15:39 |
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:37:24 |
| User entered '16:04'      | Son Do (b) (4)              | 25 Jan 2021 18:24:28 |

**US3642217**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:16:22**

[Collection Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 19:15:39 |
| User entered '21 Jan 2021 16:04' | System           | 25 Jan 2021 18:24:28 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:16:22**

[Did the participant experience any adverse events?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 May 2021 09:14:10 |
| User signature succeeded.                                  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 19:08:41 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Megan Loughran (b) (4)      | 24 Nov 2020 23:04:57 |
| User entered 'No (N)'                                      | Son Do (b) (4)              | 17 Sep 2020 16:31:46 |

US3642217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:16:22

[Adverse event](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)        | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.  | (b) (4)                 | 20 Apr 2021 15:26:19 |
| User signature succeeded.   | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4), (b) (6)        | 08 Dec 2020 19:09:48 |
| User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Piriformis syndrome, LLT: Piriformis syndrome - version MedDRA\\23.0. | Coder Import (b) (4)    | 24 Nov 2020 23:08:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)    | 24 Nov 2020 23:08:04 |
| Data point term sent to Coder   | System                  | 24 Nov 2020 23:06:50 |
| User entered 'piriformis syndrome'  | Megan Loughran (b) (4)  | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this a medically-attended AE?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

US3642217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:16:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.     |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered '06 Oct 2020' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |



**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Nov 2020 23:06:35 |

US3642217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:16:22

[Ongoing?](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   | (b) (4)                           | 20 Apr 2021 15:26:19 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an end date should be recorded. Please review and update as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).                                     | (b) (4)<br>(b) (4), (b) (6)       | 25 Jan 2021 16:10:00 |
| Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an end date should be recorded. Please review and update as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'this condition is still ongoing' (Site from DM). | Megan Loughran (b) (4)<br>(b) (4) | 22 Jan 2021 22:59:54 |
| User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an end date should be recorded. Please review and update as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).                                     | (b) (4), (b) (6)                  | 06 Jan 2021 17:40:09 |
| DataPoint Verified.  | (b) (4), (b) (6)                  | 08 Dec 2020 19:09:48 |
| User entered 'Yes (Y)'   | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

**End time (00:00-23:59)**

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Severity](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                             |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded.                          | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                                | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Is the adverse event serious?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |



**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Death](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

US3642217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:16:22

[Life threatening](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

**Hospital Admission Date** (*dd MMM yyyy*)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Admitted to ICU?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Number of Days in ICU](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    | (b) (4)                 | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 08 Dec 2020 19:09:48 |
| User entered '0'          | Megan Loughran (b) (4)  | 24 Nov 2020 23:06:35 |
|                           | (b) (4)                 |                      |



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Congenital anomaly or birth defect](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:16:22

[Other medically important event](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Relationship to investigational product](#)

| Audit                                    | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                   |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded.                | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered 'Not Related (NOT RELATED)' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:16:22

[Relationship to Study Procedure](#)

| Audit                                    | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                   |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded.                | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered 'Not Related (NOT RELATED)' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Action taken with investigational product](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.     |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered 'None (NONE)' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[None](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Concomitant Medication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    | (b) (4)                 | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 08 Dec 2020 19:09:48 |
| User entered 'I'          | Megan Loughran (b) (4)  | 24 Nov 2020 23:06:35 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:16:22

[Concomitant Procedure](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |



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Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:16:22

[Outcome](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   |                          | 20 Apr 2021 15:26:19 |
| DataPoint Verified.  |                          | 20 Apr 2021 15:24:03 |
| User signature succeeded.  | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| DataPoint Un-verified.   | (b) (4)                  |                      |
|  | Colleen McLellan (b) (4) | 15 Apr 2021 21:30:17 |
|  | (b) (4)                  |                      |
| Signature has been broken.   | Colleen McLellan (b) (4) | 15 Apr 2021 21:30:17 |
|  | (b) (4)                  |                      |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:                              | Colleen McLellan (b) (4) | 15 Apr 2021 21:30:17 |
| Data Entry Error   | (b) (4)                  |                      |
| User signature succeeded.  | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 08 Dec 2020 19:09:48 |
|  |                          |                      |
| User closed query 'Data is required. Please complete.' (Site from System).                                 | System                   | 24 Nov 2020 23:06:45 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).                     | System                   | 24 Nov 2020 23:06:45 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error | Megan Loughran (b) (4)   | 24 Nov 2020 23:06:45 |
|  | (b) (4)                  |                      |
| User opened query 'Data is required. Please complete.' (Site from System).                                 | System                   | 24 Nov 2020 23:06:35 |
| User entered empty.  | Megan Loughran (b) (4)   | 24 Nov 2020 23:06:35 |
|  | (b) (4)                  |                      |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                   | 20 Apr 2021 15:26:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:09:48 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:06:35 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:16:22

[Narrative](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   |                          | 20 Apr 2021 15:26:19 |
| DataPoint Verified.  |                          | 20 Apr 2021 15:24:03 |
| User signature succeeded.  | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| DataPoint Un-verified.   | (b) (4)                  |                      |
|  | Colleen McLellan (b) (4) | 15 Apr 2021 21:30:17 |
|  | (b) (4)                  |                      |
| Signature has been broken.   | Colleen McLellan (b) (4) | 15 Apr 2021 21:30:17 |
|  | (b) (4)                  |                      |
| User entered 'ATIENT REPORTS RIGHT HIP PAIN SINCE MAY 2020 AND WAS DIAGNOSED WITH PIRIFORMIS SYNDROME BY PCP ON 10/6/20. AE MEDICALLY ATTENDED RESULTING IN NEW MEDICATION. UPDATE: PATIENT FOLLOWED UP WITH PCP WHO RECOMMENDED ALTERNATING TYLENOL AND IBUPROFEN FOR HIP PAIN RELATED TO PIRIFORMIS SYNDROME. PATIENT REPORTS SOME IMPROVEMENT IN PAIN.' reason for change: Data Entry Error | Colleen McLellan (b) (4) | 15 Apr 2021 21:30:17 |
|  | (b) (4)                  |                      |
| User signature succeeded.  | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 08 Dec 2020 19:09:48 |
|  |                          |                      |
| User entered 'pt diagnosed with piriformis syndrome by pcp 10/6/20. medically attended resulting in new medication. hip pain started in may 2020.'   | Megan Loughran (b) (4)   | 24 Nov 2020 23:06:35 |
|  | (b) (4)                  |                      |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 24 Nov 2020 23:06:35 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Nov 2020 23:06:35 |

US3642217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

[Adverse event](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.  | (b) (4)                             | 20 Apr 2021 15:26:19 |
| User signature succeeded.   | Stephen Spector (b) (4)             | 20 Mar 2021 00:00:35 |
| User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Tingling of extremity - version MedDRA\\23.0. | Coder Import (b) (4)                | 02 Mar 2021 06:43:13 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)                | 02 Mar 2021 06:43:13 |
| DataPoint Verified.   | (b) (4), (b) (6)                    | 25 Feb 2021 21:38:04 |
| Data point term sent to Coder   | System                              | 22 Feb 2021 20:12:03 |
| Coding entries removed.   | Colleen McLellan (b) (4)            | 22 Feb 2021 20:11:25 |
| Signature has been broken.  | (b) (4)<br>Colleen McLellan (b) (4) | 22 Feb 2021 20:11:25 |
| User entered 'bilateral lower legs tingling' reason for change: New Information   | Colleen McLellan (b) (4)            | 22 Feb 2021 20:11:25 |
| User signature succeeded.   | (b) (4)<br>Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Tingling of extremity - version MedDRA\\23.0. | Coder Import (b) (4)                | 24 Jan 2021 18:48:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)                | 24 Jan 2021 18:48:49 |
| Data point term sent to Coder   | System                              | 23 Jan 2021 20:16:59 |
| User entered 'Right leg tingling'   | Nancy Tang (b) (4)                  | 23 Jan 2021 20:16:17 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this a medically-attended AE?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'    | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.     |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.        |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded.  | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered '08 Dec 2020' | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

Start time (00:00-23:59)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)        | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   |                         | 20 Apr 2021 15:26:19 |
| DataPoint Verified.  |                         | 25 Feb 2021 21:38:04 |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | (b) (4)                 | 23 Jan 2021 20:16:53 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System).  | System                  | 23 Jan 2021 20:16:53 |
| User entered empty; reason for change Data Entry Error   | Nancy Tang (b) (4)      | 23 Jan 2021 20:16:53 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).  | System                  | 23 Jan 2021 20:16:35 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System).  | System                  | 23 Jan 2021 20:16:35 |
| User entered 'UN:UN' (non-conformant).   | Nancy Tang (b) (4)      | 23 Jan 2021 20:16:35 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).  | System                  | 23 Jan 2021 20:16:17 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System                  | 23 Jan 2021 20:16:17 |
| User entered 'UK:UK' (non-conformant).   | Nancy Tang (b) (4)      | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[AE start date and time \(derived\)](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| User entered empty.                                   | System | 23 Jan 2021 20:16:53 |
| User entered '08 Dec 2020 UN:UN'<br>(non-conformant). | System | 23 Jan 2021 20:16:35 |
| User entered '08 Dec 2020 UK:UK'<br>(non-conformant). | System | 23 Jan 2021 20:16:17 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

[Ongoing?](#)

| Audit   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.  |                               | 20 Apr 2021 15:26:19 |
| 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).                            |                               | 12 Mar 2021 16:42:44 |
| 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 'AE ongoing per source.' (Site from DM). | Nancy Tang (b) (4)            | 11 Mar 2021 19:21:09 |
| DataPoint Verified.   | (b) (4), (b) (6)              | 25 Feb 2021 21:38:04 |
| 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).                            |                               | 25 Feb 2021 03:12:36 |
| User signature succeeded.   | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'  | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

End time (00:00-23:59)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)        | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.  |                         | 20 Apr 2021 15:26:19 |
| DataPoint Verified.   |                         | 25 Feb 2021 21:38:04 |
| User signature succeeded.   | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4)                 |                      |
| User entered empty; reason for change Data Entry Error                                  | System                  | 23 Jan 2021 20:16:53 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | Nancy Tang (b) (4)      | 23 Jan 2021 20:16:53 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). |                         |                      |
| User entered 'UN:UN' (non-conformant).  | System                  | 23 Jan 2021 20:16:35 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System                  | 23 Jan 2021 20:16:35 |
| User entered 'UN:UN' (non-conformant).  | Nancy Tang (b) (4)      | 23 Jan 2021 20:16:35 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). |                         |                      |
| User entered 'UK:UK' (non-conformant).  | System                  | 23 Jan 2021 20:16:17 |
|   | Nancy Tang (b) (4)      | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Jan 2021 20:16:17 |



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

[Severity](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6)           | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                             |                            | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                                |                            | 25 Feb 2021 21:38:04 |
| User signature succeeded.                          | Stephen Spector (b) (4)    | 13 Feb 2021 17:54:30 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Is the adverse event serious?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

[Death](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Life threatening](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

Hospital Discharge Date (dd MMM yyyy)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Admitted to ICU?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

[Number of Days in ICU](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Congenital anomaly or birth defect](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Other medically important event](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Relationship to investigational product](#)

| Audit                                    | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                   |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                      |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded.                | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Relationship to Study Procedure](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                         |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                            |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded.                      | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

Action taken with investigational product

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)            | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.  |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.   |                             | 25 Feb 2021 21:38:04 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| User closed query 'Per CDM: Per CCG pg.47, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).                               | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 12:48:42 |
| Query 'Per CDM: Per CCG pg.47, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'Updated per query request' (Site from DM). | Nancy Tang (b) (4)          | 03 Feb 2021 18:41:22 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error  | Nancy Tang (b) (4)          | 03 Feb 2021 18:40:53 |
| User opened query 'Per CDM: Per CCG pg.47, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).                               | (b) (4), (b) (6)            | 02 Feb 2021 11:41:22 |
| User entered 'None (NONE)'  | Nancy Tang (b) (4)          | 23 Jan 2021 20:16:17 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

None

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)                    | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                               | (b) (4)                             | 20 Apr 2021 15:26:19 |
| User signature succeeded.                            | Stephen Spector (b) (4)             | 19 Apr 2021 18:05:13 |
| DataPoint Verified.                                  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:36:25 |
| Signature has been broken.                           | Colleen McLellan (b) (4)            | 07 Apr 2021 19:45:42 |
| User entered '0' reason for change: Data Entry Error | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:45:42 |
| User signature succeeded.                            | (b) (4)<br>Stephen Spector (b) (4)  | 20 Mar 2021 00:00:35 |
| DataPoint Un-verified.                               | (b) (4)<br>Benjamin Hull (b) (4)    | 12 Mar 2021 20:31:45 |
| Signature has been broken.                           | (b) (4)<br>Benjamin Hull (b) (4)    | 12 Mar 2021 20:31:45 |
| User entered '1' reason for change: Data Entry Error | (b) (4)<br>Benjamin Hull (b) (4)    | 12 Mar 2021 20:31:45 |
| DataPoint Verified.                                  | (b) (4)<br>(b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| User signature succeeded.                            | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered '0'                                     | (b) (4)<br>Nancy Tang (b) (4)       | 23 Jan 2021 20:16:17 |



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

[Concomitant Medication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)                    | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                               | (b) (4)                             | 20 Apr 2021 15:26:19 |
| User signature succeeded.                            | Stephen Spector (b) (4)             | 19 Apr 2021 18:05:13 |
| DataPoint Verified.                                  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:36:25 |
| DataPoint Un-verified.                               | Colleen McLellan (b) (4)            | 07 Apr 2021 19:45:42 |
| Signature has been broken.                           | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:45:42 |
| User entered '1' reason for change: Data Entry Error | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:45:42 |
| DataPoint Verified.                                  | (b) (4)<br>(b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| User signature succeeded.                            | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered '0'                                     | (b) (4)<br>Nancy Tang (b) (4)       | 23 Jan 2021 20:16:17 |

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

[Concomitant Procedure](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)        | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   | (b) (4), (b) (6)        | 20 Apr 2021 15:26:19 |
| DataPoint Verified.  | (b) (4), (b) (6)        | 07 Apr 2021 21:36:25 |
| User signature succeeded.  | Stephen Spector (b) (4) | 20 Mar 2021 00:00:35 |
| User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).  | (b) (4)                 |                      |
| Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Diagnostic lower leg MRI incorrectly marked as a concomitant procedure. Corrected.' (Site from DM). | (b) (4), (b) (6)        | 15 Mar 2021 04:01:32 |
| DataPoint Un-verified.   | Benjamin Hull (b) (4)   | 12 Mar 2021 20:31:49 |
| Signature has been broken.   | (b) (4)                 |                      |
| User entered '0' reason for change: Data Entry Error   | Benjamin Hull (b) (4)   | 12 Mar 2021 20:31:45 |
| DataPoint Verified.  | (b) (4)                 |                      |
| User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).  | (b) (4), (b) (6)        | 25 Feb 2021 21:38:04 |
| User signature succeeded.  | (b) (4)                 | 25 Feb 2021 03:12:45 |
| User entered '1'   | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
|  | (b) (4)                 |                      |
|  | Nancy Tang (b) (4)      | 23 Jan 2021 20:16:17 |
|  | (b) (4)                 |                      |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

[Outcome](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.  |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded.  | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)       | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 23 Jan 2021 20:16:17 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

[Narrative](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                    | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   |                                     | 20 Apr 2021 15:26:19 |
| User closed query 'Per DM CLR: Narrative = SHE HAD HER MRI . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).  |                                     | 22 Mar 2021 05:45:13 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 20 Mar 2021 00:00:35 |
| Query 'Per DM CLR: Narrative = SHE HAD HER MRI . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'con procedure log line 1' (Site from DM).   | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 17:50:54 |
| User closed query 'Per DM CLR: Narrative = BULGING DISKS L3-5. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).   | (b) (4), (b) (6)                    | 12 Mar 2021 16:43:27 |
| Query 'Per DM CLR: Narrative = BULGING DISKS L3-5. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'Bulging disks L3-L5 is the cause of the AE so it should not be recorded as a separate AE.' (Site from DM). | Nancy Tang (b) (4)                  | 11 Mar 2021 19:22:30 |
| DataPoint Verified.  | (b) (4), (b) (6)                    | 25 Feb 2021 21:38:04 |
| User opened query 'Per DM CLR: Narrative = BULGING DISKS L3-5. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).   |                                     | 25 Feb 2021 03:12:29 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:16:22

[Narrative](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User opened query 'Per DM CLR: Narrative = SHE HAD HER MRI . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).   | (b) (4), (b) (6)         | 25 Feb 2021 03:12:17 |
| Signature has been broken.  | Colleen McLellan (b) (4) | 22 Feb 2021 20:11:25 |
| User entered 'SUBJECT REPORTED bilateral lower leg TINGLING. SHE HAD HER MRI THROUGH KAISER AND IT SHOWED "BULGING DISKS L3-5". THEY RECOMMENDED SOME SORT OF LUMBAR INJECTION FOR HER BUT SHE IS UNABLE TO GET IT AT THIS TIME BECAUSE THOSE PROCEDURES ARE ON HOLD AT KAISER DUE TO COVID-19.' reason for change: New Information | Colleen McLellan (b) (4) | 22 Feb 2021 20:11:25 |
| User signature succeeded.   | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered 'Subject reported right leg tingling. She had her MRI through Kaiser and it showed "bulging disks L3-5". They recommended some sort of lumbar injection for her but she is unable to get it at this time because those procedures are on hold at Kaiser due to COVID-19.'  | Nancy Tang (b) (4)       | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 23 Jan 2021 20:16:17 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Jan 2021 20:16:17 |



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[AEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                                |                             | 20 Apr 2021 15:26:19 |
| Reviewed for Safety.                                  |                             | 22 Mar 2021 17:49:08 |
| User signature succeeded.                             | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:38:04 |
| User entered<br>'USA-US109-2021-mRNA-1273-P301000006' | System                      | 22 Feb 2021 16:56:38 |
| User entered 'New'                                    | (b) (4), (b) (6)            | 22 Feb 2021 16:56:38 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Adverse event](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   |                                 | 20 Apr 2021 15:26:19 |
| DataPoint Verified.  |                                 | 20 Apr 2021 15:24:03 |
| User signature succeeded.  | Stephen Spector (b) (4)         | 19 Apr 2021 18:05:13 |
| User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Peripheral arterial occlusive disease, LLT: Atherosclerosis of arteries of the extremities - version MedDRA\\23.0.   | (b) (4)<br>Coder Import (b) (4) | 14 Apr 2021 12:54:54 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)            | 14 Apr 2021 12:54:54 |
| Data point term sent to Coder  | System                          | 13 Apr 2021 22:54:22 |
| User closed query 'CDM Coding, please split the term (ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION) into separate records, as 'ATHEROSCLEROSIS OF BILATERAL LEGS' and 'INTERMITTENT CLAUDICATION' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).  | System                          | 13 Apr 2021 22:53:35 |
| Query 'CDM Coding, please split the term (ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION) into separate records, as 'ATHEROSCLEROSIS OF BILATERAL LEGS' and 'INTERMITTENT CLAUDICATION' reporting each term separately with all relevant information e.g. start and stop dates etc. ' answered with 'ATHEROSCLEROSIS OF BILATERAL LEGS' and 'INTERMITTENT CLAUDICATION' reported separately per query request. ' (Site from System). | Nancy Tang (b) (4)              | 13 Apr 2021 22:53:35 |
| Data point term sent to Coder  | System                          | 13 Apr 2021 22:53:21 |
| DataPoint Un-verified.   | Nancy Tang (b) (4)              | 13 Apr 2021 22:53:01 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Adverse event](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User entered 'ATHEROSCLEROSIS OF BILATERAL LEGS' reason for change: Data Entry Error   | Nancy Tang (b) (4)       | 13 Apr 2021 22:53:01 |
| User opened query 'CDM Coding, please split the term (ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION) into separate records, as 'ATHEROSCLEROSIS OF BILATERAL LEGS' and 'INTERMITTENT CLAUDICATION' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).<br>DataPoint Verified. | Coder Import (b) (4)     | 08 Apr 2021 03:12:28 |
| Data point term sent to Coder<br>DataPoint Un-verified.  | (b) (4), (b) (6)         | 07 Apr 2021 21:36:25 |
| Coding entries removed.  | System                   | 07 Apr 2021 19:16:37 |
| Signature has been broken.   | Colleen McLellan (b) (4) | 07 Apr 2021 19:15:50 |
| User entered 'atherosclerosis of bilateral legs with intermittent claudication' reason for change: Data Entry Error  | (b) (4)                  | 07 Apr 2021 19:15:50 |
| User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Leriche syndrome, LLT: Aortoiliac occlusive disease - version MedDRA\23.0.   | Colleen McLellan (b) (4) | 07 Apr 2021 19:15:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.<br>DataPoint Verified.  | Colleen McLellan (b) (4) | 07 Apr 2021 19:15:50 |
| User signature succeeded.  | Coder Import (b) (4)     | 28 Feb 2021 11:50:22 |
| Data point term sent to Coder<br>Coding entries removed.   | (b) (4)                  | 28 Feb 2021 11:50:22 |
| Signature has been broken.   | (b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE' reason for change: Data Entry Error  | Stephen Spector (b) (4)  | 19 Feb 2021 21:10:34 |
|  | (b) (4)                  | 19 Feb 2021 00:58:11 |
|  | System                   | 19 Feb 2021 00:57:49 |
|  | Colleen McLellan (b) (4) | 19 Feb 2021 00:57:49 |
|  | (b) (4)                  | 19 Feb 2021 00:57:49 |
|  | Colleen McLellan (b) (4) | 19 Feb 2021 00:57:49 |
|  | (b) (4)                  | 19 Feb 2021 00:57:49 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Peripheral artery stenosis, LLT: Peripheral artery stenosis - version MedDRA\\23.0. | Coder Import (b) (4)     | 05 Feb 2021 19:50:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)     | 05 Feb 2021 19:50:50 |
| Data point term sent to Coder   | System                   | 05 Feb 2021 19:50:21 |
| User entered 'PERIPHERAL ARTERY STENOSIS'   | Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Was this a medically-attended AE?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                     | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                                     | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'    | (b) (4)<br>Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |
|                           | (b) (4)                             |                      |

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |  | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |  | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                                     | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                                     | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered '1 Feb 2021' | (b) (4)<br>Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |
|                           | (b) (4)                             |                      |



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Start time \(00:00-23:59\)](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |  | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Feb 2021 19:49:41 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Ongoing?](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                                    | (b) (4)                  | 20 Apr 2021 15:26:19 |
| User signature succeeded.                                 | Stephen Spector (b) (4)  | 20 Mar 2021 00:00:35 |
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| Signature has been broken.                                | Colleen McLellan (b) (4) | 22 Feb 2021 20:06:03 |
| User entered 'No (N)' reason for change: Data Entry Error | Colleen McLellan (b) (4) | 22 Feb 2021 20:06:03 |
| User signature succeeded.                                 | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'                                    | Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

If not Ongoing, end date (dd MMM yyyy)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   | (b) (4)                  | 20 Apr 2021 15:26:19 |
| User signature succeeded.                                      | Stephen Spector (b) (4)  | 20 Mar 2021 00:00:35 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| Signature has been broken.                                     | Colleen McLellan (b) (4) | 22 Feb 2021 20:06:03 |
| User entered '16 Feb 2021' reason for change: Data Entry Error | Colleen McLellan (b) (4) | 22 Feb 2021 20:06:03 |
| User signature succeeded.                                      | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered empty.  | Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

**End time (00:00-23:59)**

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |  | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Feb 2021 19:49:41 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Severity](#)

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                         |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                            |  | 25 Feb 2021 21:38:04 |
| User signature succeeded.                      | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Is the adverse event serious?](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                                     | (b) (4)                  | 20 Apr 2021 15:26:19 |
| User signature succeeded.                                  | Stephen Spector (b) (4)  | 20 Mar 2021 00:00:35 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| Signature has been broken.                                 | Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
| User signature succeeded.                                  | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'                                      | Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |



**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Death](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |  | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Life threatening](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |  | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.                                 | (b) (4), (b) (6)         | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                              | (b) (4)                  | 20 Apr 2021 15:26:19 |
| User signature succeeded.                           | Stephen Spector (b) (4)  | 20 Mar 2021 00:00:35 |
| DataPoint Verified.                                 | (b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| Signature has been broken.                          | Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
| User entered '1' reason for change: New Information | (b) (4)                  |                      |
|   | Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
| User signature succeeded.                           | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered '0'                                    | Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

Hospital Admission Date (dd MMM yyyy)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.  |                                     | 20 Apr 2021 15:26:19 |
| User signature succeeded.                                     | Stephen Spector (b) (4)             | 20 Mar 2021 00:00:35 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| Signature has been broken.                                    | Colleen McLellan (b) (4)            | 20 Feb 2021 00:37:05 |
| User entered '16 Feb 2021' reason for change: New Information | (b) (4)<br>Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
| User signature succeeded.                                     | (b) (4)<br>Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered empty.   | (b) (4)<br>Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

Hospital Discharge Date (dd MMM yyyy)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.  | (b) (4)                  | 20 Apr 2021 15:26:19 |
| User signature succeeded.                                     | Stephen Spector (b) (4)  | 20 Mar 2021 00:00:35 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| Signature has been broken.                                    | Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
| User entered '17 Feb 2021' reason for change: New Information | Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
| User signature succeeded.                                     | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered empty.   | Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |

US3642217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Admitted to ICU?](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                    | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                                     | (b) (4)                             | 20 Apr 2021 15:26:19 |
| User signature succeeded.                                  | Stephen Spector (b) (4)             | 20 Mar 2021 00:00:35 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| Signature has been broken.                                 | Colleen McLellan (b) (4)            | 20 Feb 2021 00:37:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4)<br>Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
| User signature succeeded.                                  | (b) (4)<br>Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered empty.  | (b) (4)<br>Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |

US3642217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Number of Days in ICU](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)                    | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                               | (b) (4)                             | 20 Apr 2021 15:26:19 |
| User signature succeeded.                            | Stephen Spector (b) (4)             | 20 Mar 2021 00:00:35 |
| DataPoint Verified.                                  | (b) (4), (b) (6)                    | 25 Feb 2021 21:38:04 |
| Signature has been broken.                           | Colleen McLellan (b) (4)            | 20 Feb 2021 00:37:05 |
| User entered '1' reason for change: Data Entry Error | (b) (4)<br>Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
| User signature succeeded.                            | (b) (4)<br>Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered empty.                                  | (b) (4)<br>Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Persistent or significant disability or incapacity](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |  | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |



**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Congenital anomaly or birth defect](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |  | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Other medically important event](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |  | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Relationship to investigational product](#)

| Audit                                    | User   | Time (GMT)           |
|--|--|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                   |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                      |  | 25 Feb 2021 21:38:04 |
| User signature succeeded.                | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Relationship to Study Procedure](#)

| Audit                                    | User   | Time (GMT)           |
|--|--|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                   |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                      |  | 25 Feb 2021 21:38:04 |
| User signature succeeded.                | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Action taken with investigational product](#)

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                         |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                            |  | 25 Feb 2021 21:38:04 |
| User signature succeeded.                      | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

None

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| DataPoint Verified.                                 | (b) (4), (b) (6)                    | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                              | (b) (4)                             | 20 Apr 2021 15:26:19 |
| User signature succeeded.                           | Stephen Spector (b) (4)             | 20 Mar 2021 00:00:35 |
| DataPoint Verified.                                 | (b) (4)<br>(b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| Signature has been broken.                          | Colleen McLellan (b) (4)            | 20 Feb 2021 00:37:05 |
| User entered '0' reason for change: New Information | (b) (4)<br>Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
| User signature succeeded.                           | (b) (4)<br>Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered '1'                                    | (b) (4)<br>Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Concomitant Medication](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   |                          | 20 Apr 2021 15:26:19 |
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).  |                          | 22 Mar 2021 05:46:48 |
| User signature succeeded.  | Stephen Spector (b) (4)  | 20 Mar 2021 00:00:35 |
|  | (b) (4)                  |                      |
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'ALL CON MED ASSOCIATED WITH AE: INDICATION UPDATED TO MATCH AE (VERBATIM) ' (Site from DM). | Colleen McLellan (b) (4) | 19 Mar 2021 18:07:31 |
|  | (b) (4)                  |                      |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).  | (b) (4), (b) (6)         | 09 Mar 2021 10:40:50 |
| DataPoint Verified.  |                          | 25 Feb 2021 21:38:04 |
| Signature has been broken.   | Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
|  | (b) (4)                  |                      |
| User entered '1' reason for change: New Information  | Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
|  | (b) (4)                  |                      |
| User signature succeeded.  | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
|  | (b) (4)                  |                      |
| User entered '0'   | Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |
|  | (b) (4)                  |                      |

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Form: Adverse Events (3)

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[Concomitant Procedure](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| DataPoint Verified.                                 | (b) (4), (b) (6)                    | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                              | (b) (4)                             | 20 Apr 2021 15:26:19 |
| User signature succeeded.                           | Stephen Spector (b) (4)             | 20 Mar 2021 00:00:35 |
| DataPoint Verified.                                 | (b) (4)<br>(b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| Signature has been broken.                          | Colleen McLellan (b) (4)            | 20 Feb 2021 00:37:05 |
| User entered '1' reason for change: New Information | (b) (4)<br>Colleen McLellan (b) (4) | 20 Feb 2021 00:37:05 |
| User signature succeeded.                           | (b) (4)<br>Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered '0'                                    | (b) (4)<br>Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Outcome](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.  | (b) (4)                  | 20 Apr 2021 15:26:19 |
| User signature succeeded.   | Stephen Spector (b) (4)  | 20 Mar 2021 00:00:35 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 25 Feb 2021 21:38:04 |
| Signature has been broken.  | Colleen McLellan (b) (4) | 22 Feb 2021 20:06:03 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | Colleen McLellan (b) (4) | 22 Feb 2021 20:06:03 |
| Data Entry Error  | (b) (4)                  |                      |
| User signature succeeded.   | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'    | Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                               | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |  | 25 Feb 2021 21:38:04 |
| User signature succeeded. | Stephen Spector (b) (4)                        | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Colleen McLellan (b) (4)<br>(b) (4) | 05 Feb 2021 19:49:41 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Narrative](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.  |                          | 20 Apr 2021 15:26:19 |
| User closed query 'PV Query: Please confirm If the onychomycosis, chronic kidney disease stage 3A, multiple pulmonary nodules, peripheral vascular disease, chronic tear of left anterior cruciate ligament, atherosclerosis of aorta, chronic obstructive pulmonary disease, cardiomyopathy, left bundle branch block, screening colonoscopy, heart failure with normal left ventricular ejection fraction, lumbar radiculopathy and chest pain, that are listed in discharge summary can be included under medical history. If so, please update EDC accordingly.' (Site from Safety).  |                          | 08 Apr 2021 16:32:59 |
| Query 'PV Query: Please confirm If the onychomycosis, chronic kidney disease stage 3A, multiple pulmonary nodules, peripheral vascular disease, chronic tear of left anterior cruciate ligament, atherosclerosis of aorta, chronic obstructive pulmonary disease, cardiomyopathy, left bundle branch block, screening colonoscopy, heart failure with normal left ventricular ejection fraction, lumbar radiculopathy and chest pain, that are listed in discharge summary can be included under medical history. If so, please update EDC accordingly.' answered with 'above medical conditions were confirmed with participant and added to medical history source doc and EDC' (Site from Safety). | Colleen McLellan (b) (4) | 07 Apr 2021 20:30:48 |
| User opened query 'PV Query: Please confirm If the onychomycosis, chronic kidney disease stage 3A, multiple pulmonary nodules, peripheral vascular disease, chronic tear of left anterior cruciate ligament, atherosclerosis of aorta, chronic obstructive pulmonary disease, cardiomyopathy, left bundle branch block, screening colonoscopy, heart failure with normal left ventricular ejection fraction, lumbar radiculopathy and chest pain, that are listed in discharge summary can be included under medical history. If so, please update EDC accordingly.' (Site from Safety).  | (b) (4), (b) (6)         | 29 Mar 2021 12:49:30 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Narrative](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).  | (b) (4), (b) (6)         | 22 Mar 2021 17:49:02 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).  |                          | 22 Mar 2021 17:48:59 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety).  |                          | 22 Mar 2021 17:48:56 |
| User closed query 'Per DM CLR: Narrative indicates that subject has had "STENTS." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM). User signature succeeded.   |                          | 22 Mar 2021 05:47:31 |
|  | Stephen Spector (b) (4)  | 20 Mar 2021 00:00:35 |
|  | (b) (4)                  |                      |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' answered with 'no pertinent laboratory or diagnostic data to provide ' (Site from Safety). | Colleen McLellan (b) (4) | 19 Mar 2021 20:10:47 |
|  | (b) (4)                  |                      |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Narrative](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' answered with 'COVID-19 testing performed during hospitalization sent to Safety_Moderna@iqvia.com on 19MAR2021' (Site from Safety).   | Colleen McLellan (b) (4) | 19 Mar 2021 17:55:39 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'hospital discharge summary with redacted patient identifiers sent to Safety_Moderna@iqvia.com 19MAR2021' (Site from Safety). | Colleen McLellan (b) (4) | 19 Mar 2021 17:55:00 |
| Query 'Per DM CLR: Narrative indicates that subject has had "STENTS." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'see con procedure log line 2 ' (Site from DM).  | Colleen McLellan (b) (4) | 19 Mar 2021 17:54:15 |
| User opened query 'Per DM CLR: Narrative indicates that subject has had "STENTS." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM). DataPoint Verified.  | (b) (4), (b) (6)         | 09 Mar 2021 10:40:56 |
|   |                          | 25 Feb 2021 21:38:04 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).   |                          | 25 Feb 2021 21:07:58 |

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Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:16:22

[Narrative](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).<br>User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety). | (b) (4), (b) (6)         | 25 Feb 2021 21:06:55 |
| User entered 'SUBJECT REPORTS THAT SHE WAS DIAGNOSED WITH PERIPHERAL AORTIC/ILLIAC STENOSIS CONTRIBUTING TO THE ONGOING BURNING AND TINGLING SHE HAS BEEN EXPERIENCING IN HER LEGS. SHE REQUIRED SURGERY TO HAVE STENTS PLACED ON 16FEB2021. SHE REQUIRED OVERNIGHT STAY IN ICU FOR 1 NIGHT AND WAS DISCHARGED THE FOLLOWING DAY. SHE IS RECOVERING AT HOME AND REMAINS ON STUDY.' reason for change: New Information  | Colleen McLellan (b) (4) | 22 Feb 2021 19:19:43 |
| Signature has been broken.   | Colleen McLellan (b) (4) | 20 Feb 2021 00:37:55 |
| User entered 'SUBJECT REPORTS THAT SHE WAS DIAGNOSED WITH PERIPHERAL AORTIC/ILLIAC STENOSIS CONTRIBUTING TO THE ONGOING BURNING AND TINGLING SHE HAS BEEN EXPERIENCING IN HER LEGS. SHE WILL REQUIRE SURGERY TO HAVE STENTS PLACED ON 16FEB2021. SHE DENIES ANY NEW MEDICATIONS AND HAS NOT UNDERGONE ANY NEW PROCEDURES AT THIS CURRENT TIME. SHE WILL UPDATE US AFTER SURGERY AND WE CAN REQUEST THE MEDICAL RECORDS AFTER DISCHARGE.' reason for change: Data Entry Error   | Colleen McLellan (b) (4) | 20 Feb 2021 00:37:55 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)             | 13 Feb 2021 17:54:30 |
| User entered 'Subject reports that she was diagnosed with peripheral artery stenosis contributing to the ongoing burning and tingling she has been experiencing in her legs. She will require surgery to have stents placed on 16FEB2021. She denies any new medications and has not undergone any new procedures at this current time. She will update us after surgery and we can request the medical records after discharge.' | (b) (4)<br>Colleen McLellan (b) (4) | 05 Feb 2021 19:49:41 |

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Feb 2021 00:37:05 |
| User entered '0' | System | 05 Feb 2021 19:49:41 |



**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Feb 2021 19:49:41 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Feb 2021 00:37:05 |

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:40:12 |
|                   |                  |                      |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Adverse event](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                           | 29 Apr 2021 09:40:12 |
| DataPoint Verified.  |  | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   |  | 20 Apr 2021 15:26:19 |
| DataPoint Verified.  |  | 07 Apr 2021 21:36:25 |
| User signature succeeded.  | Stephen Spector (b) (4)                    | 20 Mar 2021 00:00:35 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Postoperative wound infection, LLT: Surgical site infection - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 19 Mar 2021 07:55:07 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)            | 19 Mar 2021 07:55:07 |
| Data point term sent to Coder  | System                                     | 18 Mar 2021 17:45:24 |
| User entered 'LEFT INNER THIGH SURGICAL SITE INFECTION'  | (b) (4), (b) (6)                           | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this a medically-attended AE?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered '1 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |



**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 09:40:12 |
| User entered empty. | System           | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Ongoing?](#)

| Audit  | User                    | Time (GMT)                            |
|--|-------------------------|---------------------------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 29 Apr 2021 09:40:12                  |
| DataPoint Verified.                                      |                         | 20 Apr 2021 15:26:24                  |
| DataPoint Un-verified.                                   |                         | 20 Apr 2021 15:26:19                  |
| DataPoint Verified.                                      |                         | 07 Apr 2021 21:36:25                  |
| User signature succeeded.                                | Stephen Spector (b) (4) | 20 Mar 2021 00:00:35                  |
| User entered 'No (N)' reason for change: New Information | (b) (4)                 | (b) (4), (b) (6) 19 Mar 2021 17:37:09 |
| User entered 'Yes (Y)'                                   |                         | 18 Mar 2021 17:44:25                  |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 29 Apr 2021 09:40:12 |
| DataPoint Verified.  | (b) (4), (b) (6)        | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   | (b) (4), (b) (6)        | 20 Apr 2021 15:26:19 |
| DataPoint Verified.  | (b) (4), (b) (6)        | 07 Apr 2021 21:36:25 |
| User signature succeeded.                                      | Stephen Spector (b) (4) | 20 Mar 2021 00:00:35 |
| User entered '19 Mar 2021' reason for change: Data Entry Error | (b) (4), (b) (6)        | 19 Mar 2021 17:37:09 |
| User entered empty.  | (b) (4), (b) (6)        | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

**End time (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 09:40:12 |
| User entered empty. | System           | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Severity](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.                            |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                         |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                            |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded.                      | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Is the adverse event serious?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |



**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

Hospital Discharge Date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Admitted to ICU?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |



US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Relationship to investigational product](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.                      |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                   |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                      |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded.                | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Relationship to Study Procedure](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.                      |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                   |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                      |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded.                | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Action taken with investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.                            |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                         |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                            |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded.                      | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[None](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Concomitant Medication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Concomitant Procedure](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Outcome](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 29 Apr 2021 09:40:12 |
| DataPoint Verified.   | (b) (4), (b) (6)        | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.  | (b) (4), (b) (6)        | 20 Apr 2021 15:26:19 |
| DataPoint Verified.   | (b) (4), (b) (6)        | 07 Apr 2021 21:36:25 |
| User signature succeeded.   | Stephen Spector (b) (4) | 20 Mar 2021 00:00:35 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4), (b) (6)        | 19 Mar 2021 17:37:09 |
| New Information   | (b) (4), (b) (6)        |                      |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'                | (b) (4), (b) (6)        | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.       |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

US3642217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Narrative](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 29 Apr 2021 09:40:12 |
| DataPoint Verified.   |                             | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.  |                             | 20 Apr 2021 15:26:19 |
| DataPoint Verified.   |                             | 07 Apr 2021 21:36:25 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'Subject had surgery (angioplasty and stent insertion) on 16FEB2021 for her history of PAD where they put in 3 stents. on 01MAR2021 she had a follow up with her surgeon. The surgeon noticed that the surgical site (her left inner thigh) looked like it was infected. On 01MAR2021 she was then prescribed Doxycycline 100mg PO BID started on 01Mar2021 x 14 days for the surgical site infection. The medication was stopped on 15MAR2021. Subject was contacted on 17MAR2021 for follow up – she states that the infected surgical site is still healing but has greatly improved. Follow up on 19MAR2021 – per subject surgical site infection has resolved with no issues.' reason for change: New Information | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 17:37:09 |
| User entered 'Subject had surgery (angioplasty and stent insertion) on 16FEB2021 for her history of PAD where they put in 3 stents. on 01MAR2021 she had a follow up with her surgeon. The surgeon noticed that the surgical site (her left inner thigh) looked like it was infected. On 01MAR2021 she was then prescribed Doxycycline 100mg PO BID started on 01Mar2021 x 14 days for the surgical site infection. The medication was stopped on 15MAR2021. Subject was contacted on 17MAR2021 for follow up – she states that the infected surgical site is still healing but has greatly improved.' reason for change: Data Entry Error  | (b) (4), (b) (6)            | 18 Mar 2021 17:54:37 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:16:22

[Narrative](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Subject had surgery on 16FEB2021 for her history of PAD where they put in 3 stents. on 01MAR2021 she had a follow up with her surgeon. The surgeon noticed that the surgical site (her left inner thigh) looked like it was infected. On 01MAR2021 she was then prescribed Doxycycline 100mg PO BID started on 01Mar2021 x 14 days for the surgical site infection. The medication was stopped on 15MAR2021. Subject was contacted on 17MAR2021 for follow up – she states that the infected surgical site is still healing but has greatly improved.' | (b) (4), (b) (6) | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:40:12 |
| User entered '0'  | System           | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:40:12 |
| User entered 'I'  | System           | 18 Mar 2021 17:44:25 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:40:12 |
|                   |                  |                      |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[AEID](#)

| Audit                                 | User                    | Time (GMT)           |
|---------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                   | (b) (4), (b) (6)        | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                |                         | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                   |                         | 20 Apr 2021 15:24:03 |
| User signature succeeded.             | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered                          | (b) (4)                 |                      |
| 'USA-US109-2021-mRNA-1273-P301000006' | (b) (4), (b) (6)        | 14 Apr 2021 13:26:19 |



US3642217

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:16:22

[Adverse event](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   |                                 | 20 Apr 2021 15:26:19 |
| DataPoint Verified.  |                                 | 20 Apr 2021 15:24:03 |
| User signature succeeded.  | Stephen Spector (b) (4)         | 19 Apr 2021 18:05:13 |
| User coded data point as SOC: Vascular disorders, HLT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Intermittent claudication, LLT: Intermittent claudication - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 13 Apr 2021 22:54:36 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)            | 13 Apr 2021 22:54:36 |
| Data point term sent to Coder  | System                          | 13 Apr 2021 22:53:21 |
| User entered 'INTERMITTENT CLAUDICATION'   | Nancy Tang (b) (4)              | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this a medically-attended AE?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'No (N)'     | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'No (N)'     | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.     |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.        |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded.  | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '01 Feb 2021' | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

**Start time (00:00-23:59)**

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Apr 2021 22:52:38 |

US3642217

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:16:22

[Ongoing?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'No (N)'     | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |



**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

**If not Ongoing, end date (dd MMM yyyy)**

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.     |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.        |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded.  | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '16 Feb 2021' | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

**End time (00:00-23:59)**

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Severity](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                         |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                            |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded.                      | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

US3642217

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:16:22

[Is the adverse event serious?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Death](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

US3642217

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:16:22

[Life threatening](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'I'          | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |



US3642217

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:16:22

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.     |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.        |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded.  | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '16 Feb 2020' | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

US3642217

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:16:22

Hospital Discharge Date (dd MMM yyyy)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.     |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.        |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded.  | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '17 Feb 2020' | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Admitted to ICU?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

US3642217

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:16:22

[Number of Days in ICU](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'I'          | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

US3642217

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:16:22

[Congenital anomaly or birth defect](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

US3642217

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:16:22

[Other medically important event](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Relationship to investigational product](#)

| Audit                                    | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                   |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                      |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded.                | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |



**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Relationship to Study Procedure](#)

| Audit                                    | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                   |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                      |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded.                | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Action taken with investigational product](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                         |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                            |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded.                      | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

US3642217

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:16:22

None

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

US3642217

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:16:22

[Concomitant Medication](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'I'          | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Concomitant Procedure](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'I'          | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Outcome](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.                                 |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.                                    |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded.                              | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.    |                               | 20 Apr 2021 15:26:19 |
| DataPoint Verified.       |                               | 20 Apr 2021 15:24:03 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 13 Apr 2021 22:52:38 |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:16:22

[Narrative](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)        | 20 Apr 2021 15:26:24 |
| DataPoint Un-verified.   |                         | 20 Apr 2021 15:26:19 |
| DataPoint Verified.  |                         | 20 Apr 2021 15:24:03 |
| User signature succeeded.  | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered 'SUBJECT REPORTS THAT SHE WAS DIAGNOSED WITH PERIPHERAL AORTIC/ILLIAC STENOSIS CONTRIBUTING TO THE ONGOING BURNING AND TINGLING SHE HAS BEEN EXPERIENCING IN HER LEGS. SHE REQUIRED SURGERY TO HAVE STENTS PLACED ON 16FEB2021. SHE REQUIRED OVERNIGHT STAY IN ICU FOR 1 NIGHT AND WAS DISCHARGED THE FOLLOWING DAY. SHE IS RECOVERING AT HOME AND REMAINS ON STUDY.' | (b) (4)                 |                      |
|  | Nancy Tang (b) (4)      | 13 Apr 2021 22:52:38 |



**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 13 Apr 2021 22:52:38 |

**US3642217**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 13 Apr 2021 22:52:38 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:16:22

Were any prior/concomitant medications and/or vaccinations taken?

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 May 2021 09:14:10 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| User closed query 'Per source please add record for Atorvastatin (new dosage). ' (Site from CRA).  | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 22:49:49 |
| Query 'Per source please add record for Atorvastatin (new dosage). ' answered with 'added' (Site from CRA).  | Megan Loughran (b) (4)      | 14 Dec 2020 19:05:07 |
| User opened query 'Per source please add record for Atorvastatin (new dosage). ' (Site from CRA).  | (b) (4), (b) (6)            | 08 Dec 2020 19:18:07 |
| DataPoint Verified.  |                             | 08 Dec 2020 18:22:11 |
| User closed query 'Per CDM: Response noted, however Please consider to provide the CM details for diary dose 2 day 7 (19 oct 2020) in CM Form accordingly. Thank you. ' (Site from DM).  |                             | 26 Nov 2020 04:43:32 |
| Query 'Per CDM: Response noted, however Please consider to provide the CM details for diary dose 2 day 7 (19 oct 2020) in CM Form accordingly. Thank you. ' answered with 'participant is taking ongoing tylenol prn; this was utilized as the medication mentioned in ed diary' (Site from DM). | Megan Loughran (b) (4)      | 24 Nov 2020 23:31:01 |
| User opened query 'Per CDM: Response noted, however Please consider to provide the CM details for diary dose 2 day 7 (19 oct 2020) in CM Form accordingly. Thank you. ' (Site from DM).  | (b) (4), (b) (6)            | 19 Nov 2020 06:06:45 |
| User entered 'Yes (Y)'   | Son Do (b) (4)              | 17 Sep 2020 16:24:08 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 02 May 2021 09:46:49 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:33:54 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: LIPID<br>MODIFYING AGENTS, ATC: LIPID MODIFYING<br>AGENTS, PLAIN, ATC: HMG COA REDUCTASE<br>INHIBITORS, PRODUCT: ATORVASTATIN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 24 Nov 2020 22:44:55 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)   | 24 Nov 2020 22:44:55 |
| Data point term sent to Coder  | System                            | 24 Nov 2020 22:42:10 |
| Coding entries removed.  | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:41:29 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: LIPID<br>MODIFYING AGENTS, ATC: LIPID MODIFYING<br>AGENTS, PLAIN, ATC: HMG COA REDUCTASE<br>INHIBITORS, PRODUCT: ATORVASTATIN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 17 Sep 2020 16:25:41 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)   | 17 Sep 2020 16:25:41 |
| Data point term sent to Coder  | System                            | 17 Sep 2020 16:25:00 |
| User entered 'atorvastatin'  | Son Do (b) (4)                    | 17 Sep 2020 16:24:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:49 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:33:58 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:24:45 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 02 May 2021 09:46:49 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| User closed query 'Per CDM: Requery: Response noted, however please consider to update the indication as per MH Spelling in eCRF also. Thank you.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)       | 25 Jan 2021 04:07:25 |
| Query 'Per CDM: Requery: Response noted, however please consider to update the indication as per MH Spelling in eCRF also. Thank you.' answered with 'spelling revised' (Site from DM).  | Megan Loughran (b) (4)<br>(b) (4) | 22 Jan 2021 21:19:20 |
| User opened query 'Per CDM: Requery: Response noted, however please consider to update the indication as per MH Spelling in eCRF also. Thank you.' (Site from DM).   | (b) (4), (b) (6)                  | 15 Dec 2020 04:15:57 |
| User closed query 'Per CDM Re-Query: Please review Med Hx spelling of Hyperlipidemia. Thank you' (Site from DM).   |                                   | 15 Dec 2020 04:13:18 |
| Query 'Per CDM Re-Query: Please review Med Hx spelling of Hyperlipidemia. Thank you' answered with 'revised in source' (Site from DM).   |                                   | 14 Dec 2020 18:58:40 |
| DataPoint Verified.  | (b) (4), (b) (6)                  | 08 Dec 2020 18:33:59 |
| User opened query 'Per CDM Re-Query: Please review Med Hx spelling of Hyperlipidemia. Thank you' (Site from DM).   | (b) (4), (b) (6)                  | 26 Nov 2020 16:44:57 |
| 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, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).             |                                   | 26 Nov 2020 16:44:57 |
| Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'revised' (Site from DM). |                                   | 24 Nov 2020 22:41:35 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User entered 'hyperlipidemia' reason for change:   | Megan Loughran (b) (4) | 24 Nov 2020 22:41:29 |
| Data Entry Error   | (b) (4)                |                      |
| 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, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6)       | 19 Nov 2020 05:05:33 |
| User entered 'cholesterol'   | Son Do (b) (4)         | 17 Sep 2020 16:24:45 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:16:22

[Dose per administration](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 02 May 2021 09:46:49 |
| User signature succeeded.  | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| Signature has been broken.   | (b) (4)                 |                      |
|  | Megan Loughran (b) (4)  | 07 Apr 2021 20:39:25 |
| User signature succeeded.  | (b) (4)                 |                      |
|  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User closed query 'Per source dose is documented as '60'. Please reconcile. ' (Site from CRA).             | (b) (4)                 |                      |
| DataPoint Verified.  | (b) (4), (b) (6)        | 21 Jan 2021 22:46:42 |
|  | (b) (4), (b) (6)        | 21 Jan 2021 22:46:39 |
| Query 'Per source dose is documented as '60'. Please reconcile. ' answered with 'revised' (Site from CRA). | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:03 |
| User entered '60' reason for change: Data Entry Error  | (b) (4)                 |                      |
|  | Megan Loughran (b) (4)  | 14 Dec 2020 18:59:56 |
| User opened query 'Per source dose is documented as '60'. Please reconcile. ' (Site from CRA).             | (b) (4)                 |                      |
|  | (b) (4), (b) (6)        | 08 Dec 2020 18:33:51 |
| User entered '80' reason for change: Data Entry Error  | Son Do (b) (4)          | 12 Nov 2020 16:03:02 |
| User entered '60'  | Son Do (b) (4)          | 17 Sep 2020 16:24:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:49 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:34:02 |
| User entered 'mg (mg)'    | Son Do (b) (4)              | 17 Sep 2020 16:24:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:49 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:34:05 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:24:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 02 May 2021 09:46:49 |
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:34:08 |
| User entered 'once daily (QD)' | Son Do (b) (4)              | 17 Sep 2020 16:24:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:49 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:34:13 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:24:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 09:46:49 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:34:15 |
| User entered 'Oral (ORAL)' | Son Do (b) (4)              | 17 Sep 2020 16:24:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:49 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:34:18 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:24:45 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 02 May 2021 09:46:49 |
| DataPoint Verified.  |                                   | 18 Feb 2021 23:57:45 |
| User closed query 'Per source start date is documented as '2010'. Please reconcile. ' (Site from CRA).             |                                   | 18 Feb 2021 23:57:40 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| Query 'Per source start date is documented as '2010'. Please reconcile. ' answered with 'revised' (Site from CRA). | (b) (4)<br>Megan Loughran (b) (4) | 14 Dec 2020 19:00:07 |
| User entered 'un UNK 2010' reason for change: Data Entry Error   | Megan Loughran (b) (4)            | 14 Dec 2020 18:59:56 |
| User opened query 'Per source start date is documented as '2010'. Please reconcile. ' (Site from CRA).             | (b) (4), (b) (6)                  | 08 Dec 2020 18:34:53 |
| User entered '06 Nov 2020' reason for change: Data Entry Error   | Son Do (b) (4)                    | 12 Nov 2020 16:03:02 |
| User entered 'UN UNK 2010'   | Son Do (b) (4)                    | 17 Sep 2020 16:24:45 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:49 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:34:58 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:24:45 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:16:22

[Ongoing?](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 02 May 2021 09:46:49 |
| DataPoint Verified.   |                         | 18 Feb 2021 23:57:30 |
| User closed query 'Per source dosage was changed. Please consider changing response to 'no' for ongoing and enter stop date as applicable. ' (Site from CRA). User signature succeeded. |                         | 18 Feb 2021 23:57:28 |
|   | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
|   | (b) (4)                 |                      |
| Query 'Per source dosage was changed. Please consider changing response to 'no' for ongoing and enter stop date as applicable. ' answered with 'revised' (Site from CRA).               | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:11 |
|   | (b) (4)                 |                      |
| User entered 'No (N)' reason for change: Data Entry Error   | Megan Loughran (b) (4)  | 14 Dec 2020 18:59:56 |
|   | (b) (4)                 |                      |
| User opened query 'Per source dosage was changed. Please consider changing response to 'no' for ongoing and enter stop date as applicable. ' (Site from CRA).                           | (b) (4), (b) (6)        | 08 Dec 2020 18:37:32 |
|   |                         |                      |
| User entered 'Yes (Y)'  | Son Do (b) (4)          | 17 Sep 2020 16:24:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 02 May 2021 09:46:49 |
| DataPoint Verified.   |                                   | 18 Feb 2021 23:57:33 |
| User signature succeeded.                                     | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| User entered '06 Nov 2020' reason for change: New Information | (b) (4)<br>Megan Loughran (b) (4) | 14 Dec 2020 18:59:56 |
| User entered empty.   | Son Do (b) (4)                    | 17 Sep 2020 16:24:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:49 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:37:35 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:24:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 09:46:49 |
| User entered '1'  | System           | 17 Sep 2020 16:24:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 09:46:49 |
| User entered '1'  | System           | 17 Sep 2020 16:24:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 09:46:49 |
| User entered '804 (804)' | System           | 17 Sep 2020 16:24:45 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:42:24 |
| 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 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 25 Nov 2020 04:15:16 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)   | 25 Nov 2020 04:15:16 |
| Data point term sent to Coder  | System                            | 24 Nov 2020 22:44:14 |
| Coding entries removed.  | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:44:13 |
| User entered 'ESTRADIOL 0.1% gel' reason for change: Data Entry Error  | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:44:13 |
| 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 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 17 Sep 2020 16:26:44 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)   | 17 Sep 2020 16:26:44 |
| Data point term sent to Coder  | System                            | 17 Sep 2020 16:26:00 |
| User entered 'estradiol'   | Son Do (b) (4)                    | 17 Sep 2020 16:25:23 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:24 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:25:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:24 |
| User entered 'vaginal dryness' | Son Do (b) (4)              | 17 Sep 2020 16:25:23 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:16:22

[Dose per administration](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:42:24 |
| User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).             | (b) (4)                           | 26 Nov 2020 16:45:19 |
| Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' answered with 'revised' (Site from DM). | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:44:22 |
| User entered '1' reason for change: Data Entry Error  | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:44:13 |
| User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).             | (b) (4), (b) (6)                  | 19 Nov 2020 05:06:38 |
| User entered '.001'   | Son Do (b) (4)                    | 17 Sep 2020 16:25:23 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:16:22

[Dose unit](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:42:24 |
| User entered 'Other (OTHER)' reason for change:<br>Data Entry Error | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:44:13 |
| User entered 'mg (mg)'  | Son Do (b) (4)                    | 17 Sep 2020 16:25:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:42:24 |
| User entered 'application' reason for change: Data Entry Error | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:44:13 |
| User entered empty.  | Son Do (b) (4)                    | 17 Sep 2020 16:25:23 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:16:22

[Frequency](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:42:24 |
| User entered 'other (OTHER)' reason for change:<br>Data Entry Error | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:44:13 |
| User entered 'once daily (QD)'                                      | Son Do (b) (4)                    | 17 Sep 2020 16:25:23 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:16:22

If frequency is Other, specify

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:42:24 |
| User entered 'twice per week' reason for change:<br>Data Entry Error | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:44:13 |
| User entered empty.  | Son Do (b) (4)                    | 17 Sep 2020 16:25:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:24 |
| User entered 'Vaginal (VAGINAL)' | Son Do (b) (4)              | 17 Sep 2020 16:25:23 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:24 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:25:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:24 |
| User entered 'UN May 2020' | Son Do (b) (4)              | 17 Sep 2020 16:25:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:24 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:25:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:24 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:25:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:24 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:25:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:24 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:25:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Nov 2020 22:44:13 |
| User entered '1'    | System | 17 Sep 2020 16:25:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Nov 2020 22:44:13 |
| User entered '1'    | System | 17 Sep 2020 16:25:23 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered empty.      | System | 24 Nov 2020 22:44:13 |
| User entered '804 (804)' | System | 17 Sep 2020 16:25:23 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)        | 26 Feb 2021 22:16:07 |
| User closed query 'Please check and confirm spelling of medication and update source if applicable. ' (Site from CRA).  | (b) (4)                 | 26 Feb 2021 22:16:04 |
| User signature succeeded.   | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 14 Dec 2020 19:03:41 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)    | 14 Dec 2020 19:03:41 |
| Data point term sent to Coder   | System                  | 14 Dec 2020 19:02:24 |
| Query 'Please check and confirm spelling of medication and update source if applicable. ' answered with 'revised' (Site from CRA).  | Megan Loughran (b) (4)  | 14 Dec 2020 19:01:57 |
| Coding entries removed.   | Megan Loughran (b) (4)  | 14 Dec 2020 19:01:51 |
| User entered 'CETIRIZINE' reason for change: Data Entry Error   | Megan Loughran (b) (4)  | 14 Dec 2020 19:01:51 |
| User opened query 'Please check and confirm spelling of medication and update source if applicable. ' (Site from CRA).  | (b) (4), (b) (6)        | 08 Dec 2020 18:39:25 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 17 Sep 2020 21:39:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)    | 17 Sep 2020 21:39:42 |
| Data point term sent to Coder   | System                  | 17 Sep 2020 16:27:01 |
| User entered 'cetirizine'   | Son Do (b) (4)          | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:39:27 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                           | User                        | Time (GMT)           |
|---------------------------------|-----------------------------|----------------------|
| User signature succeeded.       | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.             | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:39:33 |
| User entered 'seasonal allergy' | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:39:38 |
| User entered '10'         | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:39:39 |
| User entered 'mg (mg)'    | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:39:41 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:39:43 |
| User entered 'once daily (QD)' | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:39:44 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:39:46 |
| User entered 'Oral (ORAL)' | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:41:12 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:41:15 |
| User entered 'UN UNK 2019' | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:41:17 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:41:18 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:41:20 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:41:27 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:26:01 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:26:01 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 17 Sep 2020 16:26:01 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 02 May 2021 09:46:54 |
| User signature succeeded.   | Stephen Spector (b) (4)         | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 08 Dec 2020 18:42:05 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC:<br>DIURETICS, ATC: POTASSIUM-SPARING<br>AGENTS, ATC: ALDOSTERONE<br>ANTAGONISTS, PRODUCT:<br>SPIRONOLACTONE - version<br>WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:27:46 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\202003.  | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:27:46 |
| Data point term sent to Coder   | System                          | 17 Sep 2020 16:27:01 |
| User entered 'spironolactone'   | Son Do (b) (4)                  | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:54 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:05 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                       | User                        | Time (GMT)           |
|-----------------------------|-----------------------------|----------------------|
| Data hard locked.           | (b) (4), (b) (6)            | 02 May 2021 09:46:54 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.         | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:05 |
| User entered 'hypertension' | Son Do (b) (4)              | 17 Sep 2020 16:26:37 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:16:22

[Dose per administration](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                  | 02 May 2021 09:46:54 |
| User signature succeeded.                             | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| DataPoint Un-verified.                                | Megan Loughran (b) (4)            | 05 Apr 2021 22:27:04 |
| Signature has been broken.                            | (b) (4)<br>Megan Loughran (b) (4) | 05 Apr 2021 22:27:04 |
| User entered '75' reason for change: Data Entry Error | (b) (4)<br>Megan Loughran (b) (4) | 05 Apr 2021 22:27:04 |
| User signature succeeded.                             | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:42:05 |
| User entered '300'                                    | Son Do (b) (4)                    | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:54 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:05 |
| User entered 'mg (mg)'    | Son Do (b) (4)              | 17 Sep 2020 16:26:37 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:54 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:05 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 02 May 2021 09:46:54 |
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:05 |
| User entered 'once daily (QD)' | Son Do (b) (4)              | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:54 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:05 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 09:46:54 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:05 |
| User entered 'Oral (ORAL)' | Son Do (b) (4)              | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:54 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:05 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 09:46:54 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:05 |
| User entered 'UN UNK 2015' | Son Do (b) (4)              | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:54 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:05 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:26:37 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:16:22

[Ongoing?](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 02 May 2021 09:46:54 |
| User signature succeeded.                                 | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.                                       | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| DataPoint Un-verified.                                    | Megan Loughran (b) (4)            | 05 Apr 2021 19:15:54 |
| Signature has been broken.                                | (b) (4)<br>Megan Loughran (b) (4) | 05 Apr 2021 19:15:54 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)<br>Megan Loughran (b) (4) | 05 Apr 2021 19:15:54 |
| User signature succeeded.                                 | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                                       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:42:05 |
| User entered 'Yes (Y)'                                    | Son Do (b) (4)                    | 17 Sep 2020 16:26:37 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:16:22

If not Ongoing, End date (dd MMM yyyy)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 02 May 2021 09:46:54 |
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| DataPoint Un-verified.   | Megan Loughran (b) (4)            | 05 Apr 2021 19:15:54 |
| Signature has been broken.                                     | (b) (4)<br>Megan Loughran (b) (4) | 05 Apr 2021 19:15:54 |
| User entered '20 Jan 2021' reason for change: Data Entry Error | (b) (4)<br>Megan Loughran (b) (4) | 05 Apr 2021 19:15:54 |
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:42:05 |
| User entered empty.  | Son Do (b) (4)                    | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:46:54 |
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:42:05 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 09:46:54 |
| User entered '1'  | System           | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 09:46:54 |
| User entered '1'  | System           | 17 Sep 2020 16:26:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 09:46:54 |
| User entered '804 (804)' | System           | 17 Sep 2020 16:26:37 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)         | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 08 Dec 2020 18:50:50 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: PSYCHOANALEPTICS, ATC:<br>ANTIDEPRESSANTS, ATC: OTHER<br>ANTIDEPRESSANTS, PRODUCT: BUPROPION -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:28:46 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:28:46 |
| Data point term sent to Coder  | System                          | 17 Sep 2020 16:28:02 |
| User entered 'bupropion'   | Son Do (b) (4)                  | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered 'anxiety'    | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered '300'        | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered 'mg (mg)'    | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered 'once daily (QD)' | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered 'Oral (ORAL)' | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered 'UN UNK 2018' | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:50 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:27:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 17 Sep 2020 16:27:06 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)         | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 08 Dec 2020 18:50:54 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CALCIUM<br>CHANNEL BLOCKERS, ATC: SELECTIVE<br>CALCIUM CHANNEL BLOCKERS WITH<br>MAINLY VASCULAR EFFECTS, ATC:<br>DIHYDROPYRIDINE DERIVATIVES, PRODUCT:<br>AMLODIPINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:28:46 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:28:46 |
| Data point term sent to Coder   | System                          | 17 Sep 2020 16:28:03 |
| User entered 'amlodopine'   | Son Do (b) (4)                  | 17 Sep 2020 16:27:38 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                       | User                        | Time (GMT)           |
|-----------------------------|-----------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.         | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered 'hypertension' | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered '10'         | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered 'mg (mg)'    | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered 'once daily (QD)' | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered 'Oral (ORAL)' | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered 'UN UNK 2018' | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:54 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:27:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:27:38 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 17 Sep 2020 16:27:38 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit  | User  | Time (GMT)                                   |
|--|---|--|
| DataPoint Verified.  | (b) (4), (b) (6)                            | 26 Feb 2021 22:16:27                         |
| User closed query 'Please check and confirm spelling and update source if applicable. ' (Site from CRA).<br>User signature succeeded.  | (b) (4)                                     | 26 Feb 2021 22:16:18                         |
|  | Stephen Spector (b) (4)                     | 13 Feb 2021 17:54:30                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ANGIOTENSIN II RECEPTOR<br>BLOCKERS (ARBS), PLAIN, ATC:<br>ANGIOTENSIN II RECEPTOR BLOCKERS<br>(ARBS), PLAIN, PRODUCT: LOSARTAN -<br>version WHODrug-Global-B3\202003.  | Coder Import (b) (4)<br>(b) (4)             | 14 Dec 2020 19:04:44                         |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\202003.   | Coder Import (b) (4)<br>(b) (4)             | 14 Dec 2020 19:04:44                         |
| Data point term sent to Coder<br>Query 'Please check and confirm spelling and update<br>source if applicable. ' answered with 'revised' (Site<br>from CRA).  | System<br>Megan Loughran (b) (4)<br>(b) (4) | 14 Dec 2020 19:03:26<br>14 Dec 2020 19:02:35 |
| Coding entries removed.  | Megan Loughran (b) (4)<br>(b) (4)           | 14 Dec 2020 19:02:31                         |
| User entered 'LOSARTaN' reason for change: Per<br>Query Resolution   | Megan Loughran (b) (4)<br>(b) (4)           | 14 Dec 2020 19:02:31                         |
| User opened query 'Please check and confirm<br>spelling and update source if applicable. ' (Site from<br>CRA).   | (b) (4), (b) (6)                            | 08 Dec 2020 18:44:13                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ANGIOTENSIN II RECEPTOR<br>BLOCKERS (ARBS), PLAIN, ATC:<br>ANGIOTENSIN II RECEPTOR BLOCKERS<br>(ARBS), PLAIN, PRODUCT: LOSARTAN<br>POTASSIUM, PRODUCTSYNONYM: LOSARTIN<br>- version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4)             | 17 Sep 2020 16:30:37                         |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\202003.   | Coder Import (b) (4)<br>(b) (4)             | 17 Sep 2020 16:30:37                         |
| Data point term sent to Coder<br>User entered 'losartin'   | System<br>Son Do (b) (4)                    | 17 Sep 2020 16:29:04<br>17 Sep 2020 16:28:13 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                       | User                    | Time (GMT)           |
|-----------------------------|-------------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded.   | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'hypertension' | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered '25'         | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'mg (mg)'    | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered empty.       | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded.      | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'once daily (QD)' | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered empty.       | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'Oral (ORAL)' | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered empty.       | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'UN UNK 2019' | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered '0'          | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'    | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered empty.       | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | Son Do (b) (4)          | 17 Sep 2020 16:28:13 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:28:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 17 Sep 2020 16:28:13 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)         | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 08 Dec 2020 18:50:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:30:37 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:30:37 |
| Data point term sent to Coder   | System                          | 17 Sep 2020 16:29:04 |
| User entered 'metformin'  | Son Do (b) (4)                  | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered 'type 2 diabetes' | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered '500'        | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered 'mg (mg)'    | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered 'twice daily (BID)' | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered 'Oral (ORAL)' | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered 'UN UNK 2016' | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:56 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:28:48 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 17 Sep 2020 16:28:48 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 18:50:59 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 24 Nov 2020 22:41:02 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)   | 24 Nov 2020 22:41:02 |
| Data point term sent to Coder  | System                            | 24 Nov 2020 22:40:02 |
| Coding entries removed.  | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:39:15 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 17 Sep 2020 16:30:38 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)   | 17 Sep 2020 16:30:38 |
| Data point term sent to Coder  | System                            | 17 Sep 2020 16:30:06 |
| User entered 'aspirin'   | Son Do (b) (4)                    | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4)                 |                      |
|   | (b) (4), (b) (6)        | 08 Dec 2020 18:50:59 |
| User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).             |                         | 26 Nov 2020 16:46:14 |
| Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' answered with 'revised' (Site from DM). | Megan Loughran (b) (4)  | 24 Nov 2020 22:39:20 |
|   | (b) (4)                 |                      |
| User entered 'heart prophylaxis' reason for change: Data Entry Error  | Megan Loughran (b) (4)  | 24 Nov 2020 22:39:15 |
|   | (b) (4)                 |                      |
| User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).             | (b) (4), (b) (6)        | 19 Nov 2020 05:09:57 |
|   |                         |                      |
| User entered 'heart disease'  | Son Do (b) (4)          | 17 Sep 2020 16:29:35 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered '81'         | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered 'mg (mg)'    | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered 'once daily (QD)' | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered 'Oral (ORAL)' | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered 'UN UNK 2015' | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:50:59 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:29:35 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 17 Sep 2020 16:29:35 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)         | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 08 Dec 2020 18:51:02 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:30:39 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:30:39 |
| Data point term sent to Coder  | System                          | 17 Sep 2020 16:30:07 |
| User entered 'magnesium'   | Son Do (b) (4)                  | 17 Sep 2020 16:30:05 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered 'supplement' | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered '250'        | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered 'mg (mg)'    | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered 'once daily (QD)' | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered 'Oral (ORAL)' | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered 'UN UNK 2019' | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:02 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:30:05 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:30:05 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 17 Sep 2020 16:30:05 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)         | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 08 Dec 2020 18:51:05 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTS YNonym: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:31:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:31:35 |
| Data point term sent to Coder  | System                          | 17 Sep 2020 16:31:09 |
| User entered 'multi vitamin'   | Son Do (b) (4)                  | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered 'supplement' | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered '200'        | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered 'IU (IU)'    | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered 'once daily (QD)' | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:16:22

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered 'Oral (ORAL)' | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered 'UN UNK 2019' | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:05 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:30:37 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:30:37 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 17 Sep 2020 16:30:37 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)         | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 08 Dec 2020 18:51:08 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: MULTIVITAMINS WITH MINERALS [UMBRELLA TERM] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 24 Nov 2020 12:20:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 24 Nov 2020 12:20:46 |
| Data point term sent to Coder   | System                          | 17 Sep 2020 16:31:10 |
| User entered 'iron d3'  | Son Do (b) (4)                  | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered 'supplement' | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered 'I'          | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered 'tablet (TABLET)' | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered 'once daily (QD)' | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered 'Oral (ORAL)' | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered 'UN UNK 2019' | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:08 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:31:08 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 17 Sep 2020 16:31:08 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)         | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 08 Dec 2020 18:51:10 |
| User coded data point as ATC: VARIOUS, ATC:<br>UNSPECIFIED HERBAL AND TRADITIONAL<br>MEDICINE, PRODUCT: CINNAMOMUM<br>VERUM, PRODUCTSYNONYM: CINNAMON<br>[CINNAMOMUM VERUM] - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:32:38 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 17 Sep 2020 16:32:38 |
| Data point term sent to Coder   | System                          | 17 Sep 2020 16:32:13 |
| User entered 'cinnamon'   | Son Do (b) (4)                  | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered 'supplement' | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered '1000'       | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered 'mg (mg)'    | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered 'once daily (QD)' | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered 'Oral (ORAL)' | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered 'UN UNK 2018' | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered '0'          | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered 'Yes (Y)'    | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered empty.       | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Dec 2020 18:51:10 |
| User entered 'No (N)'     | Son Do (b) (4)              | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 16:31:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 17 Sep 2020 16:31:36 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 02 May 2021 09:47:07 |
| DataPoint Verified.  | (b) (4)                           | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med FLU VACCINE, # 19 / (Start date 30 OCT 2020- Stop date 30 OCT 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).                                      | (b) (4)<br>(b) (4), (b) (6)       | 25 Jan 2021 06:03:40 |
| Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med FLU VACCINE, # 19 / (Start date 30 OCT 2020- Stop date 30 OCT 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'duplicate entry has been removed' (Site from DM). | Megan Loughran (b) (4)<br>(b) (4) | 22 Jan 2021 21:20:19 |
| User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med FLU VACCINE, # 19 / (Start date 30 OCT 2020- Stop date 30 OCT 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).                                      | (b) (4), (b) (6)                  | 23 Dec 2020 05:23:04 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.   | Coder Import (b) (4)<br>(b) (4)   | 14 Dec 2020 19:04:44 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.   | Coder Import (b) (4)<br>(b) (4)   | 14 Dec 2020 19:04:44 |
| Data point term sent to Coder  | System                            | 14 Dec 2020 19:04:27 |
| Coding entries removed.  | Megan Loughran (b) (4)<br>(b) (4) | 14 Dec 2020 19:04:16 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Nov 2020 16:19:31 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4) | 12 Nov 2020 16:19:31 |
| Data point term sent to Coder   | System               | 12 Nov 2020 16:03:45 |
| User entered 'flu vaccine'  | Son Do (b) (4)       | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 02 May 2021 09:47:07 |
| DataPoint Verified.       |                           | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'    | (b) (4)<br>Son Do (b) (4) | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)        | 02 May 2021 09:47:07 |
| DataPoint Verified.                                   | (b) (4)                 | 26 Feb 2021 22:16:27 |
| User signature succeeded.                             | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'prophylaxis for flu' reason for change: | (b) (4)                 |                      |
| Data Entry Error                                      | Megan Loughran (b) (4)  | 14 Dec 2020 19:04:16 |
|   | (b) (4)                 |                      |
| User entered 'vaccine'                                | Son Do (b) (4)          | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)        | 02 May 2021 09:47:07 |
| DataPoint Verified.                                    | (b) (4)                 | 26 Feb 2021 22:16:27 |
| User signature succeeded.                              | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered '0.5' reason for change: Data Entry Error | (b) (4)                 |                      |
|  | Megan Loughran (b) (4)  | 14 Dec 2020 19:04:16 |
|  | (b) (4)                 |                      |
| User entered '1'                                       | Son Do (b) (4)          | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 02 May 2021 09:47:07 |
| DataPoint Verified.  |                         | 26 Feb 2021 22:16:27 |
| User signature succeeded.                                  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'mL (mL)' reason for change: Data Entry Error | (b) (4)                 |                      |
|  | Megan Loughran (b) (4)  | 14 Dec 2020 19:04:16 |
|  | (b) (4)                 |                      |
| User entered 'Other (OTHER)'                               | Son Do (b) (4)          | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)        | 02 May 2021 09:47:07 |
| DataPoint Verified.                                    |                         | 26 Feb 2021 22:16:27 |
| User signature succeeded.                              | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered empty; reason for change Data Entry Error | (b) (4)                 |                      |
|  | Megan Loughran (b) (4)  | 14 Dec 2020 19:04:16 |
|  | (b) (4)                 |                      |
| User entered 'injection'                               | Son Do (b) (4)          | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                      | Time (GMT)           |
|----------------------------|---------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)          | 02 May 2021 09:47:07 |
| DataPoint Verified.        |                           | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered 'once (ONCE)' | (b) (4)<br>Son Do (b) (4) | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 02 May 2021 09:47:07 |
| DataPoint Verified.       |                           | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Son Do (b) (4) | 12 Nov 2020 16:03:43 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)          | 02 May 2021 09:47:07 |
| DataPoint Verified.                          | (b) (4)                   | 26 Feb 2021 22:16:27 |
| User signature succeeded.                    | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4)<br>Son Do (b) (4) | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 02 May 2021 09:47:07 |
| DataPoint Verified.       | (b) (4)                   | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Son Do (b) (4) | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                      | Time (GMT)           |
|----------------------------|---------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)          | 02 May 2021 09:47:07 |
| DataPoint Verified.        |                           | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered '30 Oct 2020' | (b) (4)<br>Son Do (b) (4) | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 02 May 2021 09:47:07 |
| DataPoint Verified.       |                           | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Son Do (b) (4) | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 02 May 2021 09:47:07 |
| DataPoint Verified.       |                           | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | (b) (4)<br>Son Do (b) (4) | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                      | Time (GMT)           |
|----------------------------|---------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)          | 02 May 2021 09:47:07 |
| DataPoint Verified.        |                           | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered '30 Oct 2020' | (b) (4)<br>Son Do (b) (4) | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 02 May 2021 09:47:07 |
| DataPoint Verified.       |                           | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)   | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | (b) (4)<br>Son Do (b) (4) | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:07 |
| User entered empty. | System           | 12 Nov 2020 16:03:43 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:07 |
| User entered empty. | System           | 12 Nov 2020 16:03:43 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:07 |
| User entered empty. | System           | 12 Nov 2020 16:03:43 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 09:47:10 |
| 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)<br>(b) (4)     | 19 Mar 2021 22:26:40 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)     | 19 Mar 2021 22:26:40 |
| Data point term sent to Coder   | System                              | 19 Mar 2021 22:25:53 |
| Coding entries removed.   | Nancy Tang (b) (4)                  | 19 Mar 2021 22:25:26 |
| DataPoint Verified.   | (b) (4), (b) (6)                    | 26 Feb 2021 22:16:27 |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)  | 13 Feb 2021 17:54:30 |
| User closed query 'Per DM CLR: Con Med TYLENOL was added/changed on 19 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).   | (b) (4), (b) (6)                    | 12 Feb 2021 06:02:23 |
| Query 'Per DM CLR: Con Med TYLENOL was added/changed on 19 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'PER SOURCE THIS MEDICATION IS REPORTED TO BE TAKEN PRN FOR ON GOING HIP PAIN PRESENT PRIOR TO ENROLLMENT. START DATE OF CONDITION: UNK MAY 2020. NO EXACERBATION REPORTED. ' (Site from DM). | Colleen McLellan (b) (4)<br>(b) (4) | 11 Feb 2021 19:29:45 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User opened query 'Per DM CLR: Con Med<br>TYLENOL was added/changed on 19 SEP 2020.<br>Please clarify if there was a<br>WORSENING/EXACERBATION of the medical<br>history condition requiring a change in medications.<br>If yes, please add the applicable AE entry or explain<br>the reason for change in regimen.<br />' (Site from<br>DM). | (b) (4), (b) (6)                 | 26 Jan 2021 14:48:55 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OTHER<br>ANALGESICS AND ANTIPYRETICS, ATC:<br>ANILIDES, PRODUCT: PARACETAMOL,<br>PRODUCTSYNONYM: TYLENOL - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)  | 16 Nov 2020 23:09:48 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)  | 16 Nov 2020 23:09:48 |
| Data point term sent to Coder   | System                           | 16 Nov 2020 23:09:20 |
| User entered 'TYLENOL'  | Benjamin Hull (b) (4)<br>(b) (4) | 16 Nov 2020 23:09:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 02 May 2021 09:47:10 |
| DataPoint Verified.       | (b) (4)                                     | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)                     | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | (b) (4)<br>Benjamin Hull (b) (4)<br>(b) (4) | 16 Nov 2020 23:09:18 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User  | Time (GMT)           |
|--|---|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                            | 02 May 2021 09:47:10 |
| User signature succeeded.  | Stephen Spector (b) (4)                     | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)                 | 07 Apr 2021 21:34:48 |
| 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 if appropriate.' (Site from DM).   |   | 22 Mar 2021 05:48:40 |
| 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 if appropriate.' answered with 'Conmed was taken for HIP PAIN (RIGHT) listed in Medical history. See Medical history.' (Site from DM). | Nancy Tang (b) (4)                          | 19 Mar 2021 22:25:54 |
| DataPoint Un-verified.   | Nancy Tang (b) (4)                          | 19 Mar 2021 22:25:26 |
| Signature has been broken.   | Nancy Tang (b) (4)                          | 19 Mar 2021 22:25:26 |
| User entered 'HIP PAIN (RIGHT)' reason for change: Data Entry Error  | Nancy Tang (b) (4)                          | 19 Mar 2021 22:25:26 |
| 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 details to the AE eCRF if appropriate.' (Site from DM).   | (b) (4), (b) (6)                            | 10 Mar 2021 09:28:26 |
| DataPoint Verified.  | (b) (4), (b) (6)                            | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4)                     | 13 Feb 2021 17:54:30 |
| User entered 'HIP PAIN'  | (b) (4)<br>Benjamin Hull (b) (4)<br>(b) (4) | 16 Nov 2020 23:09:18 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:16:22

[Dose per administration](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 02 May 2021 09:47:10 |
| DataPoint Verified.  | (b) (4)                 | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).             | (b) (4), (b) (6)        | 25 Jan 2021 06:04:15 |
| User entered '1000' reason for change: Data Entry Error  | Megan Loughran (b) (4)  | 22 Jan 2021 21:26:26 |
| 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 'revised' (Site from DM). | Megan Loughran (b) (4)  | 22 Jan 2021 21:24:53 |
| User entered '500' reason for change: Data Entry Error   | Megan Loughran (b) (4)  | 22 Jan 2021 21:24:49 |
| 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)        | 23 Dec 2020 05:24:44 |
| User entered '200'   | Benjamin Hull (b) (4)   | 16 Nov 2020 23:09:18 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:16:22

[Dose unit](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 02 May 2021 09:47:10 |
| DataPoint Verified.       |   | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)                     | 13 Feb 2021 17:54:30 |
| User entered 'mg (mg)'    | (b) (4)<br>Benjamin Hull (b) (4)<br>(b) (4) | 16 Nov 2020 23:09:18 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:16:22

If dose unit is Other, specify

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 02 May 2021 09:47:10 |
| DataPoint Verified.       |   | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)                     | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Benjamin Hull (b) (4)<br>(b) (4) | 16 Nov 2020 23:09:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)         | 02 May 2021 09:47:10 |
| DataPoint Verified.                               | (b) (4)                  | 26 Feb 2021 22:16:27 |
| User signature succeeded.                         | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| User entered 'as needed (PRN)' reason for change: | (b) (4)                  |                      |
| Data Entry Error                                  | Colleen McLellan (b) (4) | 11 Feb 2021 19:28:46 |
| User entered 'twice daily (BID)'                  | (b) (4)                  |                      |
|   | Benjamin Hull (b) (4)    | 16 Nov 2020 23:09:18 |
|   | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 02 May 2021 09:47:10 |
| DataPoint Verified.       | (b) (4)                                     | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)                     | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Benjamin Hull (b) (4)<br>(b) (4) | 16 Nov 2020 23:09:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 02 May 2021 09:47:10 |
| DataPoint Verified.        |   | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4)                     | 13 Feb 2021 17:54:30 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Benjamin Hull (b) (4)<br>(b) (4) | 16 Nov 2020 23:09:18 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:16:22

If route of administration is Other, specify

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 02 May 2021 09:47:10 |
| DataPoint Verified.       |   | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)                     | 13 Feb 2021 17:54:30 |
| User entered empty.       | (b) (4)<br>Benjamin Hull (b) (4)<br>(b) (4) | 16 Nov 2020 23:09:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 02 May 2021 09:47:10 |
| DataPoint Verified.        | (b) (4)                                     | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4)                     | 13 Feb 2021 17:54:30 |
| User entered '19 Sep 2020' | (b) (4)<br>Benjamin Hull (b) (4)<br>(b) (4) | 16 Nov 2020 23:09:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 02 May 2021 09:47:10 |
| DataPoint Verified.       |   | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)                     | 13 Feb 2021 17:54:30 |
| User entered '0'          | (b) (4)<br>Benjamin Hull (b) (4)<br>(b) (4) | 16 Nov 2020 23:09:18 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:16:22

[Ongoing?](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 02 May 2021 09:47:10 |
| DataPoint Verified.  | (b) (4)                 | 26 Feb 2021 22:16:27 |
| User signature succeeded.                                  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'No (N)' reason for change: Data Entry Error  | (b) (4)                 |                      |
|  | Megan Loughran (b) (4)  | 24 Nov 2020 22:50:17 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4)                 |                      |
|  | Megan Loughran (b) (4)  | 24 Nov 2020 22:49:25 |
| User entered 'No (N)'                                      | Benjamin Hull (b) (4)   | 16 Nov 2020 23:09:18 |
|  | (b) (4)                 |                      |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:16:22

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 02 May 2021 09:47:10 |
| DataPoint Verified.  | (b) (4)                 | 26 Feb 2021 22:16:27 |
| User signature succeeded.                                      | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered '19 Sep 2020' reason for change: Data Entry Error | (b) (4)                 |                      |
|  | Megan Loughran (b) (4)  | 24 Nov 2020 22:50:17 |
| User entered empty; reason for change Data Entry Error         | (b) (4)                 |                      |
|  | Megan Loughran (b) (4)  | 24 Nov 2020 22:49:25 |
| User entered '19 Sep 2020'                                     | (b) (4)                 |                      |
|  | Benjamin Hull (b) (4)   | 16 Nov 2020 23:09:18 |
|  | (b) (4)                 |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 02 May 2021 09:47:10 |
| DataPoint Verified.       |   | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4)                     | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | (b) (4)<br>Benjamin Hull (b) (4)<br>(b) (4) | 16 Nov 2020 23:09:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:10 |
| User entered empty. | System           | 11 Feb 2021 19:28:46 |
| User entered '2'    | System           | 16 Nov 2020 23:09:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:10 |
| User entered empty. | System           | 11 Feb 2021 19:28:46 |
| User entered '1'    | System           | 16 Nov 2020 23:09:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 09:47:10 |
| User entered empty.      | System           | 11 Feb 2021 19:28:46 |
| User entered '804 (804)' | System           | 16 Nov 2020 23:09:18 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User  | Time (GMT)                                   |
|---|---|--|
| 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)<br>(b) (4)               | 15 Apr 2021 21:25:43                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)<br>(b) (4)               | 15 Apr 2021 21:25:43                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 15 Apr 2021 21:24:29<br>15 Apr 2021 21:23:57 |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)            | 13 Feb 2021 17:54:30                         |
| User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).   | (b) (4), (b) (6)<br>(b) (4), (b) (6)          | 12 Feb 2021 06:03:36                         |
| Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' answered with 'TYLENOL FOR ONGOING MEDICAL CONDITION (HIP PAIN START: UNK MAY 2020).' (Site from DM). | Colleen McLellan (b) (4)<br>(b) (4)           | 11 Feb 2021 19:25:30                         |
| User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).   | (b) (4), (b) (6)                              | 26 Jan 2021 14:48:45                         |
| DataPoint Verified.   |   | 08 Dec 2020 19:04:26                         |

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| 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)<br>(b) (4)   | 24 Nov 2020 22:52:05 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)   | 24 Nov 2020 22:52:05 |
| Data point term sent to Coder  | System                            | 24 Nov 2020 22:51:25 |
| DataPoint activated with code reason code Data required.   | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| Data point term sent to Coder  | System                            | 24 Nov 2020 22:49:23 |
| DataPoint inactivated with code reason code Data not required.   | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| 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)<br>(b) (4)   | 16 Nov 2020 23:13:52 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)   | 16 Nov 2020 23:13:52 |
| Data point term sent to Coder  | System                            | 16 Nov 2020 23:13:21 |
| User entered 'TYLENOL'   | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

[Prophylaxis](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered 'No (N)'  | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded.  | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4) | 15 Apr 2021 21:23:57 |
| Signature has been broken.   | Colleen McLellan (b) (4) | 15 Apr 2021 21:23:57 |
| User entered 'PIRIFORMIS SYNDROME' reason for change: Data Entry Error | Colleen McLellan (b) (4) | 15 Apr 2021 21:23:57 |
| User signature succeeded.  | Stephen Spector (b) (4)  | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 08 Dec 2020 19:04:26 |
| DataPoint activated with code reason code Data required.               | Megan Loughran (b) (4)   | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required.         | Megan Loughran (b) (4)   | 24 Nov 2020 22:49:11 |
| User entered 'HIP PAIN'  | Benjamin Hull (b) (4)    | 16 Nov 2020 23:12:22 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

[Dose per administration](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| User entered '1000' reason for change: Data Entry Error        | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:52:37 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered '500'   | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

[Dose unit](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered 'mg (mg)'   | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

If dose unit is Other, specify

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered empty.  | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

[Frequency](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| User entered 'as needed (PRN)' reason for change:<br>Data Entry Error | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:52:37 |
| DataPoint activated with code reason code Data<br>required.           | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not<br>required.     | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered 'twice daily (BID)'                                      | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

If frequency is Other, specify

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered empty.  | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

[Route of administration](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered 'Oral (ORAL)'                                     | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

If route of administration is Other, specify

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered empty.  | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:52:37 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered '07 Oct 2020'                                     | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

Start date completely unknown

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered '0'   | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered 'Yes (Y)'   | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered empty.  | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

[Was this medication taken for solicited event?](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:04:26 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 22:49:11 |
| User entered 'No (N)'  | Benjamin Hull (b) (4)<br>(b) (4)  | 16 Nov 2020 23:12:22 |

US3642217

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User entered empty.  | System                 | 24 Nov 2020 22:52:37 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4) | 24 Nov 2020 22:49:11 |
| User entered '2'   | System                 | 16 Nov 2020 23:12:22 |

US3642217

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User entered empty.  | System                 | 24 Nov 2020 22:52:37 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4) | 24 Nov 2020 22:49:11 |
| User entered 'I'   | System                 | 16 Nov 2020 23:12:22 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:16:22

[Interval Dosage Definition \(derived\)](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User entered empty.  | System                 | 24 Nov 2020 22:52:37 |
| DataPoint activated with code reason code Data required.       | Megan Loughran (b) (4) | 24 Nov 2020 22:50:32 |
| DataPoint inactivated with code reason code Data not required. | Megan Loughran (b) (4) | 24 Nov 2020 22:49:11 |
| User entered '804 (804)'                                       | System                 | 16 Nov 2020 23:12:22 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded.   | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User coded data point as ATC: SYSTEMIC<br>HORMONAL PREPARATIONS, EXCL. SEX<br>HORMONES AND INSULINS, ATC:<br>CORTICOSTEROIDS FOR SYSTEMIC USE, ATC:<br>CORTICOSTEROIDS FOR SYSTEMIC USE,<br>PLAIN, ATC: GLUCOCORTICOID, PRODUCT:<br>PREDNISONE - version<br>WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4)   | 25 Nov 2020 02:47:29 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\202003.   | Coder Import (b) (4)<br>(b) (4)   | 25 Nov 2020 02:47:29 |
| Data point term sent to Coder   | System                            | 24 Nov 2020 23:08:52 |
| User entered 'prednisone'   | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                              | User                              | Time (GMT)           |
|------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded.          | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered 'piriformis syndrome' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered '40'         | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered 'mg (mg)'    | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded.      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered 'once daily (QD)' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered 'Oral (ORAL)' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered '06 Oct 2020' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered '08 Oct 2020' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:16 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:31 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 09:47:16 |
| User entered '1'  | System           | 24 Nov 2020 23:08:42 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 09:47:16 |
| User entered '1'  | System           | 24 Nov 2020 23:08:42 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 09:47:16 |
| User entered '804 (804)' | System           | 24 Nov 2020 23:08:42 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded.   | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User coded data point as ATC: SYSTEMIC<br>HORMONAL PREPARATIONS, EXCL. SEX<br>HORMONES AND INSULINS, ATC:<br>CORTICOSTEROIDS FOR SYSTEMIC USE, ATC:<br>CORTICOSTEROIDS FOR SYSTEMIC USE,<br>PLAIN, ATC: GLUCOCORTICOID, PRODUCT:<br>PREDNISONE - version<br>WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4)   | 25 Nov 2020 02:47:29 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\202003.   | Coder Import (b) (4)<br>(b) (4)   | 25 Nov 2020 02:47:29 |
| Data point term sent to Coder   | System                            | 24 Nov 2020 23:09:52 |
| User entered 'prednisone'   | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                              | User                              | Time (GMT)           |
|------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded.          | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered 'piriformis syndrome' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered '20'         | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered 'mg (mg)'    | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:16:22

If dose unit is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded.      | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered 'once daily (QD)' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered 'Oral (ORAL)' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered '09 Oct 2020' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered '0'          | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered '11 Oct 2020' | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 09:47:19 |
| User signature succeeded. | Stephen Spector (b) (4)           | 13 Feb 2021 17:54:30 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 08 Dec 2020 19:03:35 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 09:47:19 |
| User entered '1'  | System           | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 09:47:19 |
| User entered '1'  | System           | 24 Nov 2020 23:09:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 09:47:19 |
| User entered '804 (804)' | System           | 24 Nov 2020 23:09:13 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                | 26 Feb 2021 22:16:27 |
| User signature succeeded.   | Stephen Spector (b) (4)         | 13 Feb 2021 17:54:30 |
| User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM). | (b) (4)<br>(b) (4), (b) (6)     | 12 Feb 2021 06:04:57 |
| Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.                               | Colleen McLellan (b) (4)        | 11 Feb 2021 19:18:59 |
| ' answered with 'SUBJECT DID NOT REPORT ANY NEW DIAGNOSES OR REPORTS OR WORSENING/EXACERBATED MEDICAL CONDITION. ' (Site from DM).  | (b) (4)                         |                      |
| User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM). | (b) (4), (b) (6)                | 26 Jan 2021 14:46:15 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)<br>(b) (4) | 14 Dec 2020 19:02:06 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)<br>(b) (4) | 14 Dec 2020 19:02:06 |
| Data point term sent to Coder   | System                          | 14 Dec 2020 19:01:23 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit                       | User                              | Time (GMT)           |
|-----------------------------|-----------------------------------|----------------------|
| User entered 'atorvastatin' | Megan Loughran (b) (4)<br>(b) (4) | 14 Dec 2020 19:00:53 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'No (N)'     | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                         | User                    | Time (GMT)           |
|-------------------------------|-------------------------|----------------------|
| DataPoint Verified.           | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded.     | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'hyperlipidemia' | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered '80'         | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'mg (mg)'    | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:16:22

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered empty.       | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:16:22

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded.      | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'once daily (QD)' | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered empty.       | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'Oral (ORAL)' | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:16:22

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered empty.       | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered '06 Nov 2020' | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:16:22

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered '0'          | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User entered empty.       | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:16:22

[Was this medication taken for solicited event?](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)        | 26 Feb 2021 22:16:27 |
| User signature succeeded.  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                 |                      |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 14 Dec 2020 19:04:29 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Megan Loughran (b) (4)  | 14 Dec 2020 19:04:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                 |                      |
| User entered empty.  | System                  | 14 Dec 2020 19:00:53 |
|  | Megan Loughran (b) (4)  | 14 Dec 2020 19:00:53 |
|  | (b) (4)                 |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 14 Dec 2020 19:00:53 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 14 Dec 2020 19:00:53 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 14 Dec 2020 19:00:53 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                                       | Time (GMT)                                   |
|---|--|--|
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 07 Apr 2021 19:20:40                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)            | 07 Apr 2021 19:20:40                         |
| Data point term sent to Coder Coding entries removed.   | System Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:19:54<br>07 Apr 2021 19:19:27 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 19 Mar 2021 17:58:35                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)            | 19 Mar 2021 17:58:35                         |
| Data point term sent to Coder Coding entries removed.   | System Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 17:58:20<br>19 Mar 2021 17:57:26 |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)         | 06 Mar 2021 01:50:28                         |
| DataPoint Verified.   | (b) (4), (b) (6)<br>(b) (4)                | 26 Feb 2021 22:16:27                         |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 22 Feb 2021 20:26:02                         |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit  | User   | Time (GMT)   |
|--|--|--|
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.<br>Data point term sent to Coder<br>Coding entries removed.  | Coder Import (b) (4)<br>(b) (4)<br>System<br>Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:26:02<br><br>22 Feb 2021 20:25:28<br>22 Feb 2021 20:25:22 |
| User coded data point as ATC: BLOOD AND<br>BLOOD FORMING ORGANS, ATC:<br>ANTITHROMBOTIC AGENTS, ATC:<br>ANTITHROMBOTIC AGENTS, ATC: PLATELET<br>AGGREGATION INHIBITORS EXCL. HEPARIN,<br>PRODUCT: CLOPIDOGREL BISULFATE,<br>PRODUCTSYNONYM: PLAVIX - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 20 Feb 2021 00:44:02   |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.<br>Data point term sent to Coder<br>User entered 'PLAVIX'  | Coder Import (b) (4)<br>(b) (4)<br>System<br>Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:44:02<br><br>20 Feb 2021 00:43:33<br>20 Feb 2021 00:43:12 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:16:22

[Prophylaxis](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)  | 08 Apr 2021 23:59:42 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).                   |                          | 07 Apr 2021 07:10:21 |
| Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'changed to no' (Site from DM). | Megan Loughran (b) (4)   | 05 Apr 2021 19:21:18 |
| DataPoint Un-verified.  | Megan Loughran (b) (4)   | 05 Apr 2021 19:21:11 |
| Signature has been broken.  | Megan Loughran (b) (4)   | 05 Apr 2021 19:21:11 |
| User entered 'No (N)' reason for change: Data Entry Error   | Megan Loughran (b) (4)   | 05 Apr 2021 19:21:11 |
| User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).                   | (b) (4), (b) (6)         | 04 Apr 2021 04:05:37 |
| User signature succeeded.   | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Colleen McLellan (b) (4) | 22 Feb 2021 20:25:22 |
| User entered 'No (N)'   | Colleen McLellan (b) (4) | 20 Feb 2021 00:43:12 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF<br>BILATERAL LEGS WITH INTERMITTENT<br>CLAUDICATION' reason for change: Data Entry<br>Error | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:19:27 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 17:57:26 |
| Signature has been broken.   | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 17:57:26 |
| User entered 'AORTO-LEFT UNI-ILIAC<br>OCCLUSIVE DISEASE' reason for change: Data<br>Entry Error                              | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 17:57:26 |
| User signature succeeded.  | Stephen Spector (b) (4)<br>(b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4), (b) (6)                    | 26 Feb 2021 22:16:27 |
| User entered 'iliac stent prophylaxis' reason for<br>change: Data Entry Error  | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:25:22 |
| User entered 'AORTO-LEFT UNI-ILIAC<br>OCCLUSIVE DISEASE'   | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:43:12 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '75'         | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:43:12 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'mg (mg)'    | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:43:12 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:16:22

If dose unit is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:43:12 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                                | Time (GMT)           |
|--------------------------------|-------------------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once daily (QD)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:43:12 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:16:22

If frequency is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:43:12 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Oral (ORAL)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:43:12 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:43:12 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)                  |                      |
|                            | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '17 Feb 2021' | Colleen McLellan (b) (4) | 20 Feb 2021 00:43:12 |
|                            | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                  |                      |
|                           | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4) | 20 Feb 2021 00:43:12 |
|                           | (b) (4)                  |                      |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:16:22

[Ongoing?](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).  | (b) (4), (b) (6)         | 08 Apr 2021 06:55:45 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'the medication is ongoing at this time. ' (Site from DM). | Megan Loughran (b) (4)   | 07 Apr 2021 20:36:54 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).  | (b) (4), (b) (6)         | 04 Apr 2021 04:05:50 |
| User signature succeeded.  | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Yes (Y)'   | Colleen McLellan (b) (4) | 20 Feb 2021 00:43:12 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:43:12 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:43:12 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Feb 2021 00:43:12 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Feb 2021 00:43:12 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Feb 2021 00:43:12 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)     | 08 Apr 2021 06:30:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)     | 08 Apr 2021 06:30:42 |
| Data point term sent to Coder   | System                              | 07 Apr 2021 19:43:51 |
| Data point term sent to Coder   | System                              | 07 Apr 2021 19:09:20 |
| Coding entries removed.   | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:08:32 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)     | 30 Mar 2021 14:16:06 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)     | 30 Mar 2021 14:16:06 |
| Data point term sent to Coder   | System                              | 19 Mar 2021 17:58:20 |
| Coding entries removed.   | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 17:57:36 |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4), (b) (6)<br>(b) (4)         | 26 Feb 2021 22:16:27 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)     | 20 Feb 2021 13:56:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)     | 20 Feb 2021 13:56:49 |
| Data point term sent to Coder   | System                              | 20 Feb 2021 00:46:35 |
| User entered 'GABAPENTIN'   | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:45:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:45:57 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| User entered 'BILATERAL LEG TINGLING'<br>reason for change: Data Entry Error                    | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:43:23 |
| User entered 'bilateral lower leg tingling' reason for<br>change: Data Entry Error              | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:08:32 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 17:57:36 |
| Signature has been broken.  | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 17:57:36 |
| User entered 'AORTO-LEFT UNI-ILIAC<br>OCCLUSIVE DISEASE' reason for change: Data<br>Entry Error | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 17:57:36 |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4), (b) (6)                    | 26 Feb 2021 22:16:27 |
| User entered 'BURNING IN LOWER<br>EXTREMITIES'  | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:45:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '300'        | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:45:57 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:16:22

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'mg (mg)'    | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:45:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:45:57 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:16:22

[Frequency](#)

| Audit                                  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.              | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                    | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'three times daily (TID)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:45:57 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:16:22

If frequency is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:45:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Oral (ORAL)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:45:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:45:57 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)                  |                      |
|                            | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '17 Feb 2021' | Colleen McLellan (b) (4) | 20 Feb 2021 00:45:57 |
|                            | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                  |                      |
|                           | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          |                          |                      |
|                           | Colleen McLellan (b) (4) | 20 Feb 2021 00:45:57 |
|                           | (b) (4)                  |                      |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:16:22

[Ongoing?](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)           | 23 Apr 2021 20:51:21 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 20 Apr 2021 19:14:32 |
| DataPoint Un-verified.   | Megan Loughran (b) (4)            | 19 Apr 2021 20:28:49 |
| Signature has been broken.   | (b) (4)<br>Megan Loughran (b) (4) | 19 Apr 2021 20:28:49 |
| User entered 'No (N)' reason for change: Data Entry Error  | (b) (4)<br>Megan Loughran (b) (4) | 19 Apr 2021 20:28:49 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).  | (b) (4), (b) (6)                  | 08 Apr 2021 06:55:51 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'AE bilateral lower leg tingling ongoing ' (Site from DM). | Colleen McLellan (b) (4)          | 07 Apr 2021 19:08:45 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).  | (b) (4), (b) (6)                  | 04 Apr 2021 04:06:02 |
| User signature succeeded.  | Stephen Spector (b) (4)           | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)       | 26 Feb 2021 22:16:27 |
| User entered 'Yes (Y)'   | Colleen McLellan (b) (4)          | 20 Feb 2021 00:45:57 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:16:22

If not Ongoing, End date (dd MMM yyyy)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                                      | Stephen Spector (b) (4)  | 23 Apr 2021 20:51:21 |
| DataPoint Verified.  | (b) (4)                  |                      |
|  | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| DataPoint Un-verified.   |                          |                      |
|  | Megan Loughran (b) (4)   | 19 Apr 2021 20:28:49 |
|  | (b) (4)                  |                      |
| Signature has been broken.                                     | Megan Loughran (b) (4)   | 19 Apr 2021 20:28:49 |
|  | (b) (4)                  |                      |
| User entered '12 Apr 2021' reason for change: Data Entry Error | Megan Loughran (b) (4)   | 19 Apr 2021 20:28:49 |
|  | (b) (4)                  |                      |
| User signature succeeded.                                      | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
|  |                          |                      |
| User entered empty.  | Colleen McLellan (b) (4) | 20 Feb 2021 00:45:57 |
|  | (b) (4)                  |                      |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:45:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 20 Feb 2021 00:45:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Feb 2021 00:45:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Feb 2021 00:45:57 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 09:47:28 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 07 Apr 2021 19:20:39 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | (b) (4)                  |                      |
| Data point term sent to Coder Coding entries removed.  | System                   | 07 Apr 2021 19:19:53 |
|  | Colleen McLellan (b) (4) | 07 Apr 2021 19:18:59 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | (b) (4)                  |                      |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)     | 19 Mar 2021 18:13:37 |
| Data point term sent to Coder Coding entries removed.  | (b) (4)                  |                      |
|  | System                   | 19 Mar 2021 17:58:18 |
|  | Colleen McLellan (b) (4) | 19 Mar 2021 17:57:51 |
| User signature succeeded.  | (b) (4)                  |                      |
|  | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)                  |                      |
|  | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 20 Feb 2021 00:49:58 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | (b) (4)                  |                      |
| Data point term sent to Coder User entered 'ACETAMINOPHEN'   | System                   | 20 Feb 2021 00:48:38 |
|  | Colleen McLellan (b) (4) | 20 Feb 2021 00:47:59 |
|  | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION' reason for change: Data Entry Error  | Colleen McLellan (b) (4)            | 07 Apr 2021 19:18:59 |
| 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 if appropriate.' (Site from DM).   | (b) (4), (b) (6)                    | 22 Mar 2021 05:49:21 |
| 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 if appropriate.' answered with 'indication updated to match AE "AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE"' (Site from DM). | Colleen McLellan (b) (4)            | 19 Mar 2021 17:58:02 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4)            | 19 Mar 2021 17:57:51 |
| Signature has been broken.   | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 17:57:51 |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE' reason for change: Data Entry Error  | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 17:57:51 |
| 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 details to the AE eCRF if appropriate.' (Site from DM).   | (b) (4), (b) (6)                    | 10 Mar 2021 09:28:47 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'POST-OPERATIVE PAIN'   | Colleen McLellan (b) (4)            | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '650'        | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'mg (mg)'    | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded.    | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'other (OTHER)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded.    | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'EVERY 4 HOURS' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Oral (ORAL)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '17 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:28 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:28 |
| User entered empty. | System           | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:28 |
| User entered empty. | System           | 20 Feb 2021 00:47:59 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:28 |
| User entered empty. | System           | 20 Feb 2021 00:47:59 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User  | Time (GMT)                                   |
|---|---|--|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 08 Apr 2021 10:26:49                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)               | 08 Apr 2021 10:26:49                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:18:52<br>07 Apr 2021 19:18:50 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 24 Mar 2021 08:58:35                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)               | 24 Mar 2021 08:58:35                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 17:58:20<br>19 Mar 2021 17:58:13 |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)            | 06 Mar 2021 01:50:28                         |
| DataPoint Verified.   | (b) (4), (b) (6)<br>(b) (4)                   | 26 Feb 2021 22:16:27                         |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 20 Feb 2021 00:51:02                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)               | 20 Feb 2021 00:51:02                         |
| Data point term sent to Coder User entered 'TRAMADOL'   | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:41<br>20 Feb 2021 00:48:47 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:48:47 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF<br>BILATERAL LEGS WITH INTERMITTENT<br>CLAUDICATION' reason for change: Data Entry<br>Error | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:18:50 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 17:58:13 |
| Signature has been broken.   | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 17:58:13 |
| User entered 'AORTO-LEFT UNI-ILIAC<br>OCCLUSIVE DISEASE' reason for change: Data<br>Entry Error                              | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 17:58:13 |
| User signature succeeded.  | Stephen Spector (b) (4)<br>(b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4), (b) (6)                    | 26 Feb 2021 22:16:27 |
| User entered 'POST-OPERATIVE PAIN'   | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:48:47 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '50'         | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:48:47 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:16:22

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'mg (mg)'    | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:48:47 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:16:22

If dose unit is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:48:47 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                                 | User                                | Time (GMT)           |
|---------------------------------------|-------------------------------------|----------------------|
| User signature succeeded.             | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                   | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'four times daily (QID)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:48:47 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:16:22

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:48:47 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Oral (ORAL)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:48:47 |

US3642217

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:48:47 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:16:22

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)                  |                      |
|                            | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4) | 20 Feb 2021 00:48:47 |
|                            | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                  |                      |
|                           | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4) | 20 Feb 2021 00:48:47 |
|                           | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Yes (Y)'    | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:48:47 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:48:47 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:16:22

[Was this medication taken for solicited event?](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)                  |                      |
|  | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                   | 20 Feb 2021 00:48:53 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                   | 20 Feb 2021 00:48:53 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Colleen McLellan (b) (4) | 20 Feb 2021 00:48:53 |
|  | (b) (4)                  |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                   | 20 Feb 2021 00:48:47 |
| User entered empty.  | Colleen McLellan (b) (4) | 20 Feb 2021 00:48:47 |
|  | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 20 Feb 2021 00:48:47 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Feb 2021 00:48:47 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Feb 2021 00:48:47 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                               | Time (GMT)                                   |
|---|------------------------------------|--|
| Data hard locked.   | (b) (4), (b) (6)                   | 02 May 2021 09:47:31                         |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 06:31:42                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 06:31:42                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:18:52<br>07 Apr 2021 19:18:41 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 30 Mar 2021 14:29:32                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 30 Mar 2021 14:29:32                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 19 Mar 2021 17:59:21<br>19 Mar 2021 17:58:23 |
| User signature succeeded.   | (b) (4)<br>Stephen Spector (b) (4) | 06 Mar 2021 01:50:28                         |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)        | 26 Feb 2021 22:16:27                         |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 20 Feb 2021 13:56:50                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 20 Feb 2021 13:56:50                         |
| Data point term sent to Coder User entered 'HEPARIN'  | System<br>Colleen McLellan (b) (4) | 20 Feb 2021 00:50:42<br>20 Feb 2021 00:49:57 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:16:22

[Prophylaxis](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded.   | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).                   | (b) (4)<br>(b) (4), (b) (6)         | 08 Apr 2021 06:56:21 |
| DataPoint Verified.   | (b) (4), (b) (6)                    | 07 Apr 2021 21:34:48 |
| Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'updated to no' (Site from DM). | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 18:55:27 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)            | 07 Apr 2021 18:55:21 |
| Signature has been broken.  | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 18:55:21 |
| User entered 'No (N)' reason for change: Data Entry Error   | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 18:55:21 |
| User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).                   | (b) (4), (b) (6)                    | 04 Apr 2021 04:06:14 |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4), (b) (6)                    | 26 Feb 2021 22:16:27 |
| User entered 'Yes (Y)'  | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:57 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF<br>BILATERAL LEGS WITH INTERMITTENT<br>CLAUDICATION' reason for change: Data Entry<br>Error | Colleen McLellan (b) (4)            | 07 Apr 2021 19:18:41 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4)            | 19 Mar 2021 17:58:23 |
| Signature has been broken.   | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 17:58:23 |
| User entered 'AORTO-LEFT UNI-ILIAC<br>OCCLUSIVE DISEASE' reason for change: Data<br>Entry Error                              | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 17:58:23 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'DVT PROPHYLAXIS'   | Colleen McLellan (b) (4)            | 20 Feb 2021 00:49:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '5,000'      | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded.    | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Other (OTHER)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:57 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:16:22

If dose unit is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'UNITS'      | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:57 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:16:22

[Frequency](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)            | 02 May 2021 09:47:31 |
| User signature succeeded.                           | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                                 | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 22:16:27 |
| User entered 'twice daily (BID)' reason for change: | Colleen McLellan (b) (4)    | 22 Feb 2021 20:23:56 |
| Data Entry Error                                    | (b) (4)                     |                      |
| User entered 'once (ONCE)'                          | Colleen McLellan (b) (4)    | 20 Feb 2021 00:49:57 |
|   | (b) (4)                     |                      |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:16:22

If frequency is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:57 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                      | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded.                  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '17 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:57 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:16:22

If not Ongoing, End date (dd MMM yyyy)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded.   | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System). | System                              | 20 Feb 2021 00:50:07 |
| User entered '17 Feb 2021' reason for change: Data Entry Error                                      | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:50:07 |
| User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System). | System                              | 20 Feb 2021 00:49:57 |
| User entered empty.   | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:31 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:49:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:31 |
| User entered '2'    | System           | 22 Feb 2021 20:23:56 |
| User entered empty. | System           | 20 Feb 2021 00:49:57 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:31 |
| User entered '1'    | System           | 22 Feb 2021 20:23:56 |
| User entered empty. | System           | 20 Feb 2021 00:49:57 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 09:47:31 |
| User entered '804 (804)' | System           | 22 Feb 2021 20:23:56 |
| User entered empty.      | System           | 20 Feb 2021 00:49:57 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                               | Time (GMT)                                   |
|---|------------------------------------|--|
| Data hard locked.   | (b) (4), (b) (6)                   | 02 May 2021 09:47:38                         |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 09:38:48                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 09:38:48                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:18:51<br>07 Apr 2021 19:18:32 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 24 Mar 2021 11:17:32                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 24 Mar 2021 11:17:32                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 19 Mar 2021 17:59:21<br>19 Mar 2021 17:58:42 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 19 Mar 2021 11:44:31                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 19 Mar 2021 11:44:31                         |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[Name of Medication](#)

| Audit                                | User                     | Time (GMT)           |
|--------------------------------------|--------------------------|----------------------|
| User signature succeeded.            | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                  | (b) (4)                  |                      |
|                                      | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| Data point term sent to Coder        | System                   | 22 Feb 2021 20:25:28 |
| Data point term sent to Coder        | System                   | 20 Feb 2021 00:52:42 |
| User entered 'PLAVIX (LOADING DOSE)' | Colleen McLellan (b) (4) | 20 Feb 2021 00:52:28 |
|                                      | (b) (4)                  |                      |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:16:22

[Prophylaxis](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).                   |                                     | 09 Apr 2021 08:32:47 |
| User signature succeeded.   | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'updated to no' (Site from DM). | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 18:55:45 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)            | 07 Apr 2021 18:55:40 |
| Signature has been broken.  | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 18:55:40 |
| User entered 'No (N)' reason for change: Data Entry Error   | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 18:55:40 |
| User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).                   | (b) (4), (b) (6)                    | 04 Apr 2021 04:06:26 |
| User signature succeeded.   | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:24:59 |
| User entered 'No (N)'   | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION' reason for change: Data Entry Error  | Colleen McLellan (b) (4)            | 07 Apr 2021 19:18:32 |
| User closed query 'Per DM CLR: Indication =ILIAC STENT PROPHYLAXIS. Please review if this indication should be updated to remove the Prophylaxis indication as there is an AE AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE recorded that matches this medication and is during the same timeframe. If yes, please update eCRF as appropriate.' (Site from DM).   | (b) (4), (b) (6)                    | 22 Mar 2021 05:50:01 |
| Query 'Per DM CLR: Indication =ILIAC STENT PROPHYLAXIS. Please review if this indication should be updated to remove the Prophylaxis indication as there is an AE AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE recorded that matches this medication and is during the same timeframe. If yes, please update eCRF as appropriate.' answered with 'medication started post operatively for prophylaxis to maintain iliac stent patency. Initial post op loading dose 300mg followed by daily maintenance dose of 75mg.' (Site from DM). | Colleen McLellan (b) (4)            | 19 Mar 2021 18:01:40 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4)            | 19 Mar 2021 17:58:42 |
| Signature has been broken.   | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 17:58:42 |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE' reason for change: Data Entry Error  | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 17:58:42 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit   | User  | Time (GMT)                                   |
|---|---|--|
| User opened query 'Per DM CLR: Indication =ILIAC STENT PROPHYLAXIS. Please review if this indication should be updated to remove the Prophylaxis indication as there is an AE AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE recorded that matches this medication and is during the same timeframe. If yes, please update eCRF as appropriate.' (Site from DM).<br>User signature succeeded. | (b) (4), (b) (6)                            | 10 Mar 2021 09:29:25                         |
| DataPoint Verified.   | Stephen Spector (b) (4)<br>(b) (4), (b) (6) | 06 Mar 2021 01:50:28<br>26 Feb 2021 22:16:27 |
| User entered 'iliac stent prophylaxis' reason for change: Data Entry Error  | Colleen McLellan (b) (4)<br>(b) (4)         | 22 Feb 2021 20:24:59                         |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE'   | Colleen McLellan (b) (4)<br>(b) (4)         | 20 Feb 2021 00:52:28                         |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '300'        | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:16:22

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'mg (mg)'    | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Oral (ORAL)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:16:22

If route of administration is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:38 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:52:28 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:38 |
| User entered empty. | System           | 20 Feb 2021 00:52:28 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:38 |
| User entered empty. | System           | 20 Feb 2021 00:52:28 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:38 |
| User entered empty. | System           | 20 Feb 2021 00:52:28 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                               | Time (GMT)                                   |
|---|------------------------------------|--|
| Data hard locked.   | (b) (4), (b) (6)                   | 02 May 2021 09:47:42                         |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 05:17:57                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 05:17:57                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:18:52<br>07 Apr 2021 19:18:23 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 22 Mar 2021 04:10:45                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 22 Mar 2021 04:10:45                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:02:39<br>19 Mar 2021 18:01:53 |
| User signature succeeded.   | (b) (4)<br>Stephen Spector (b) (4) | 06 Mar 2021 01:50:28                         |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)        | 26 Feb 2021 22:16:27                         |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 20 Feb 2021 13:53:47                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 20 Feb 2021 13:53:47                         |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit                             | User                     | Time (GMT)           |
|-----------------------------------|--------------------------|----------------------|
| Data point term sent to Coder     | System                   | 20 Feb 2021 00:54:43 |
| User entered 'CEFAZOLIN (PRE-OP)' | Colleen McLellan (b) (4) | 20 Feb 2021 00:53:52 |
|                                   | (b) (4)                  |                      |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:16:22

[Prophylaxis](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded.   | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).                   | (b) (4)<br>(b) (4), (b) (6)         | 08 Apr 2021 07:03:15 |
| DataPoint Verified.   | (b) (4), (b) (6)                    | 07 Apr 2021 21:34:48 |
| Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'updated to no' (Site from DM). | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 18:56:01 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)            | 07 Apr 2021 18:55:56 |
| Signature has been broken.  | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 18:55:56 |
| User entered 'No (N)' reason for change: Data Entry Error   | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 18:55:56 |
| User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).                   | (b) (4), (b) (6)                    | 04 Apr 2021 04:06:36 |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4), (b) (6)                    | 26 Feb 2021 22:16:27 |
| User entered 'Yes (Y)'  | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF<br>BILATERAL LEGS WITH INTERMITTENT<br>CLAUDICATION' reason for change: Data Entry<br>Error | Colleen McLellan (b) (4)            | 07 Apr 2021 19:18:23 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4)            | 19 Mar 2021 18:01:53 |
| Signature has been broken.   | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:01:53 |
| User entered 'AORTO-LEFT UNI-ILIAC<br>OCCLUSIVE DISEASE' reason for change: Data<br>Entry Error                              | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:01:53 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'SURGICAL-INFECTION<br>PROPHYLAXIS'   | Colleen McLellan (b) (4)            | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '2'          | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'g (g)'      | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:42 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:42 |
| User entered empty. | System           | 20 Feb 2021 00:53:52 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:42 |
| User entered empty. | System           | 20 Feb 2021 00:53:52 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:42 |
| User entered empty. | System           | 20 Feb 2021 00:53:52 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                               | Time (GMT)                                   |
|---|------------------------------------|--|
| Data hard locked.   | (b) (4), (b) (6)                   | 02 May 2021 09:47:49                         |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 05:17:53                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 05:17:53                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:18:51<br>07 Apr 2021 19:18:15 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 22 Mar 2021 04:02:40                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 22 Mar 2021 04:02:40                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:02:39<br>19 Mar 2021 18:02:07 |
| User signature succeeded.   | (b) (4)<br>Stephen Spector (b) (4) | 06 Mar 2021 01:50:28                         |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)        | 26 Feb 2021 22:16:27                         |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 20 Feb 2021 13:53:48                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 20 Feb 2021 13:53:48                         |

US3642217

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[Name of Medication](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| Data point term sent to Coder      | System                   | 20 Feb 2021 00:55:43 |
| User entered 'CEFAZOLIN (POST-OP)' | Colleen McLellan (b) (4) | 20 Feb 2021 00:55:18 |
|                                    | (b) (4)                  |                      |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:16:22

[Prophylaxis](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded.   | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).                   | (b) (4)<br>(b) (4), (b) (6)         | 08 Apr 2021 07:03:20 |
| DataPoint Verified.   | (b) (4), (b) (6)                    | 07 Apr 2021 21:34:48 |
| Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'updated to no' (Site from DM). | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 18:56:28 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)            | 07 Apr 2021 18:56:23 |
| Signature has been broken.  | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 18:56:23 |
| User entered 'No (N)' reason for change: Data Entry Error   | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 18:56:23 |
| User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#3) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).                   | (b) (4), (b) (6)                    | 04 Apr 2021 04:06:47 |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4), (b) (6)                    | 26 Feb 2021 22:16:27 |
| User entered 'Yes (Y)'  | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 02 May 2021 09:47:49 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 08 Apr 2021 23:59:42 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION' reason for change: Data Entry Error | Colleen McLellan (b) (4)    | 07 Apr 2021 19:18:15 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:02:07 |
| Signature has been broken.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:02:07 |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE' reason for change: Data Entry Error                           | Colleen McLellan (b) (4)    | 19 Mar 2021 18:02:07 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 22:16:27 |
| User entered 'POST-SURGICAL INFECTION PROPHYLAXIS'  | Colleen McLellan (b) (4)    | 20 Feb 2021 00:55:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '2'          | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'g (g)'      | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded.    | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'other (OTHER)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:16:22

[If frequency is Other, specify](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded.    | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'EVERY 8 HOURS' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '17 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:49 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 20 Feb 2021 00:55:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:49 |
| User entered empty. | System           | 20 Feb 2021 00:55:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:49 |
| User entered empty. | System           | 20 Feb 2021 00:55:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:49 |
| User entered empty. | System           | 20 Feb 2021 00:55:18 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit  | User  | Time (GMT)                                   |
|--|---|--|
| Data hard locked.  | (b) (4), (b) (6)                              | 02 May 2021 09:47:52                         |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 08 Apr 2021 06:24:45                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)               | 08 Apr 2021 06:24:45                         |
| Data point term sent to Coder Coding entries removed.  | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:18:51<br>07 Apr 2021 19:18:05 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 30 Mar 2021 14:03:22                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)               | 30 Mar 2021 14:03:22                         |
| Data point term sent to Coder Coding entries removed.  | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 18:02:40<br>19 Mar 2021 18:02:34 |
| User signature succeeded.  | Stephen Spector (b) (4)<br>(b) (4)            | 06 Mar 2021 01:50:28                         |
| DataPoint Verified.  | (b) (4), (b) (6)<br>(b) (4)                   | 26 Feb 2021 22:16:27                         |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 26 Feb 2021 07:33:14                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)               | 26 Feb 2021 07:33:14                         |
| Data point term sent to Coder User entered 'fentanyl (pf) bolus'   | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:31<br>22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF<br>BILATERAL LEGS WITH INTERMITTENT<br>CLAUDICATION' reason for change: Data Entry<br>Error | Colleen McLellan (b) (4)            | 07 Apr 2021 19:18:05 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4)            | 19 Mar 2021 18:02:34 |
| Signature has been broken.   | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:02:34 |
| User entered 'AORTO-LEFT UNI-ILIAC<br>OCCLUSIVE DISEASE' reason for change: Data<br>Entry Error                              | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:02:34 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'STENT GRAFT PLACEMENT'   | Colleen McLellan (b) (4)            | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '100'        | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'ug (ug)'    | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:52 |
| User entered empty. | System           | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:52 |
| User entered empty. | System           | 22 Feb 2021 20:27:13 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:52 |
| User entered empty. | System           | 22 Feb 2021 20:27:13 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User  | Time (GMT)                                   |
|---|---|--|
| Data hard locked.   | (b) (4), (b) (6)                              | 02 May 2021 09:47:55                         |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 08 Apr 2021 07:30:37                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)               | 08 Apr 2021 07:30:37                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:18:51<br>07 Apr 2021 19:17:58 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 07 Apr 2021 15:49:04                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)               | 07 Apr 2021 15:49:04                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 18:03:47<br>19 Mar 2021 18:02:43 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 15 Mar 2021 07:09:59                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)               | 15 Mar 2021 07:09:59                         |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)            | 06 Mar 2021 01:50:28                         |
| DataPoint Verified.   | (b) (4), (b) (6)                              | 26 Feb 2021 22:16:27                         |
| Data point term sent to Coder   | System  | 22 Feb 2021 20:29:43                         |
| Data point term sent to Coder   | System  | 22 Feb 2021 20:28:42                         |
| User entered 'LIDOCAINE'  | Colleen McLellan (b) (4)<br>(b) (4)           | 22 Feb 2021 20:27:50                         |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 02 May 2021 09:47:55 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 08 Apr 2021 23:59:42 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION' reason for change: Data Entry Error | Colleen McLellan (b) (4)    | 07 Apr 2021 19:17:58 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:02:43 |
| Signature has been broken.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:02:43 |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE' reason for change: Data Entry Error                           | Colleen McLellan (b) (4)    | 19 Mar 2021 18:02:43 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 22:16:27 |
| User entered 'STENT GRAFT PLACEMENT' reason for change: Data Entry Error  | Colleen McLellan (b) (4)    | 22 Feb 2021 20:28:50 |
| User entered '50'   | Colleen McLellan (b) (4)    | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '50'         | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'ug (ug)'    | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:47:55 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:55 |
| User entered empty. | System           | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:55 |
| User entered empty. | System           | 22 Feb 2021 20:27:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:47:55 |
| User entered empty. | System           | 22 Feb 2021 20:27:50 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                               | Time (GMT)                                   |
|---|------------------------------------|--|
| Data hard locked.   | (b) (4), (b) (6)                   | 02 May 2021 09:48:05                         |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 09:45:38                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 09:45:38                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:18:52<br>07 Apr 2021 19:17:52 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 25 Mar 2021 09:00:01                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 25 Mar 2021 09:00:01                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:03:44<br>19 Mar 2021 18:02:55 |
| User signature succeeded.   | (b) (4)<br>Stephen Spector (b) (4) | 06 Mar 2021 01:50:28                         |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 05 Mar 2021 05:33:46                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 05 Mar 2021 05:33:46                         |
| DataPoint Verified.   | (b) (4), (b) (6)                   | 26 Feb 2021 22:16:27                         |
| Data point term sent to Coder User entered 'PROPOFOL'   | System<br>Colleen McLellan (b) (4) | 22 Feb 2021 20:28:42<br>22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 02 May 2021 09:48:05 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 08 Apr 2021 23:59:42 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION' reason for change: Data Entry Error | Colleen McLellan (b) (4)    | 07 Apr 2021 19:17:52 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:02:55 |
| Signature has been broken.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:02:55 |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE' reason for change: Data Entry Error                           | Colleen McLellan (b) (4)    | 19 Mar 2021 18:02:55 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 22:16:27 |
| User entered 'STENT GRAFT PLACEMENT'  | Colleen McLellan (b) (4)    | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '150'        | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'mg (mg)'    | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:05 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:05 |
| User entered empty. | System           | 22 Feb 2021 20:28:36 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:05 |
| User entered empty. | System           | 22 Feb 2021 20:28:36 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:05 |
| User entered empty. | System           | 22 Feb 2021 20:28:36 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User  | Time (GMT)                                   |
|---|---|--|
| Data hard locked.   | (b) (4), (b) (6)                              | 02 May 2021 09:48:08                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE<br>RELAXANTS, ATC: MUSCLE RELAXANTS,<br>PERIPHERALLY ACTING AGENTS, ATC:<br>OTHER QUATERNARY AMMONIUM<br>COMPOUNDS, PRODUCT: ROCURONIUM -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 08 Apr 2021 09:49:43                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)               | 08 Apr 2021 09:49:43                         |
| Data point term sent to Coder<br>Coding entries removed.  | System<br>Colleen McLellan (b) (4)            | 07 Apr 2021 19:18:51<br>07 Apr 2021 19:17:44 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE<br>RELAXANTS, ATC: MUSCLE RELAXANTS,<br>PERIPHERALLY ACTING AGENTS, ATC:<br>OTHER QUATERNARY AMMONIUM<br>COMPOUNDS, PRODUCT: ROCURONIUM -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 08 Mar 2021 08:00:01                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)               | 08 Mar 2021 08:00:01                         |
| User signature succeeded.   | Stephen Spector (b) (4)                       | 06 Mar 2021 01:50:28                         |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)                   | 26 Feb 2021 22:16:27                         |
| Data point term sent to Coder<br>User entered 'ROCURONIUM'  | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:44<br>22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4)            | 07 Apr 2021 19:17:44 |
| Signature has been broken.   | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:17:44 |
| User entered 'ATHEROSCLEROSIS OF<br>BILATERAL LEGS WITH INTERMITTENT<br>CLAUDICATION' reason for change: Data Entry<br>Error | (b) (4)<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:17:44 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'STENT GRAFT PLACEMENT'   | Colleen McLellan (b) (4)            | 22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '50'         | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'mg (mg)'    | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:16:22

If frequency is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:08 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:08 |
| User entered empty. | System           | 22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:08 |
| User entered empty. | System           | 22 Feb 2021 20:29:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:08 |
| User entered empty. | System           | 22 Feb 2021 20:29:38 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                               | Time (GMT)                                   |
|---|------------------------------------|--|
| Data hard locked.   | (b) (4), (b) (6)                   | 02 May 2021 09:48:12                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CARDIAC<br>THERAPY, ATC: CARDIAC STIMULANTS<br>EXCL. CARDIAC GLYCOSIDES, ATC:<br>ADRENERGIC AND DOPAMINERGIC AGENTS,<br>PRODUCT: PHENYLEPHRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 09:38:47                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 09:38:47                         |
| Data point term sent to Coder<br>Coding entries removed.  | System<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:17:43<br>07 Apr 2021 19:17:37 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CARDIAC<br>THERAPY, ATC: CARDIAC STIMULANTS<br>EXCL. CARDIAC GLYCOSIDES, ATC:<br>ADRENERGIC AND DOPAMINERGIC AGENTS,<br>PRODUCT: PHENYLEPHRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 24 Mar 2021 10:45:32                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 24 Mar 2021 10:45:32                         |
| Data point term sent to Coder<br>Coding entries removed.  | System<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:03:42<br>19 Mar 2021 18:03:21 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CARDIAC<br>THERAPY, ATC: CARDIAC STIMULANTS<br>EXCL. CARDIAC GLYCOSIDES, ATC:<br>ADRENERGIC AND DOPAMINERGIC AGENTS,<br>PRODUCT: PHENYLEPHRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 19 Mar 2021 11:35:31                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 19 Mar 2021 11:35:31                         |
| User signature succeeded.   | Stephen Spector (b) (4)            | 06 Mar 2021 01:50:28                         |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)        | 26 Feb 2021 22:16:27                         |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit                         | User                     | Time (GMT)           |
|-------------------------------|--------------------------|----------------------|
| Data point term sent to Coder | System                   | 22 Feb 2021 20:30:45 |
| User entered 'PHENYLEPHRINE'  | Colleen McLellan (b) (4) | 22 Feb 2021 20:30:31 |
|                               | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 02 May 2021 09:48:12 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 08 Apr 2021 23:59:42 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION' reason for change: Data Entry Error | Colleen McLellan (b) (4)    | 07 Apr 2021 19:17:37 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:03:21 |
| Signature has been broken.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:03:21 |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE' reason for change: Data Entry Error                           | Colleen McLellan (b) (4)    | 19 Mar 2021 18:03:21 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 22:16:27 |
| User entered 'STENT GRAFT PLACEMENT'  | Colleen McLellan (b) (4)    | 22 Feb 2021 20:30:31 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '400'        | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'ug (ug)'    | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:12 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:12 |
| User entered empty. | System           | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:12 |
| User entered empty. | System           | 22 Feb 2021 20:30:31 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:12 |
| User entered empty. | System           | 22 Feb 2021 20:30:31 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                               | Time (GMT)                                   |
|---|------------------------------------|--|
| Data hard locked.   | (b) (4), (b) (6)                   | 02 May 2021 09:48:17                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CARDIAC<br>THERAPY, ATC: CARDIAC STIMULANTS<br>EXCL. CARDIAC GLYCOSIDES, ATC:<br>ADRENERGIC AND DOPAMINERGIC AGENTS,<br>PRODUCT: EPHEDRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 06:21:40                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 06:21:40                         |
| Data point term sent to Coder<br>Coding entries removed.  | System<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:17:41<br>07 Apr 2021 19:17:28 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CARDIAC<br>THERAPY, ATC: CARDIAC STIMULANTS<br>EXCL. CARDIAC GLYCOSIDES, ATC:<br>ADRENERGIC AND DOPAMINERGIC AGENTS,<br>PRODUCT: EPHEDRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 22 Mar 2021 04:48:45                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 22 Mar 2021 04:48:45                         |
| Data point term sent to Coder<br>Coding entries removed.  | System<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:03:47<br>19 Mar 2021 18:03:30 |
| User signature succeeded.   | (b) (4)<br>Stephen Spector (b) (4) | 06 Mar 2021 01:50:28                         |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)        | 26 Feb 2021 22:16:27                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CARDIAC<br>THERAPY, ATC: CARDIAC STIMULANTS<br>EXCL. CARDIAC GLYCOSIDES, ATC:<br>ADRENERGIC AND DOPAMINERGIC AGENTS,<br>PRODUCT: EPHEDRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 22 Feb 2021 21:41:07                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 22 Feb 2021 21:41:07                         |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit                         | User                     | Time (GMT)           |
|-------------------------------|--------------------------|----------------------|
| Data point term sent to Coder | System                   | 22 Feb 2021 20:31:46 |
| User entered 'EPHEDRINE'      | Colleen McLellan (b) (4) | 22 Feb 2021 20:31:18 |
|                               | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 02 May 2021 09:48:17 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 08 Apr 2021 23:59:42 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION' reason for change: Data Entry Error | Colleen McLellan (b) (4)    | 07 Apr 2021 19:17:28 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:03:30 |
| Signature has been broken.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:03:30 |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE' reason for change: Data Entry Error                           | Colleen McLellan (b) (4)    | 19 Mar 2021 18:03:30 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 22:16:27 |
| User entered 'STENT GRAFT PLACEMENT'  | Colleen McLellan (b) (4)    | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '2.5'        | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'mg (mg)'    | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:17 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:17 |
| User entered empty. | System           | 22 Feb 2021 20:31:18 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:17 |
| User entered empty. | System           | 22 Feb 2021 20:31:18 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:17 |
| User entered empty. | System           | 22 Feb 2021 20:31:18 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DEXMEDETOMIDINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)     | 08 Apr 2021 06:13:01 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)     | 08 Apr 2021 06:13:01 |
| Data point term sent to Coder   | System                              | 07 Apr 2021 19:17:42 |
| Coding entries removed.   | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:17:19 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DEXMEDETOMIDINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)     | 22 Mar 2021 04:22:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)     | 22 Mar 2021 04:22:44 |
| Data point term sent to Coder   | System                              | 19 Mar 2021 18:03:47 |
| Coding entries removed.   | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 18:03:46 |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4), (b) (6)<br>(b) (4)         | 26 Feb 2021 22:16:27 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DEXMEDETOMIDINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)     | 22 Feb 2021 21:24:03 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)     | 22 Feb 2021 21:24:03 |
| Data point term sent to Coder   | System                              | 22 Feb 2021 20:32:50 |
| User entered 'DEXMEDETOMIDINE'  | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 02 May 2021 09:48:22 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION' reason for change: Data Entry Error  | Colleen McLellan (b) (4)    | 07 Apr 2021 19:17:19 |
| User closed query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' (Site from DM).                   | (b) (4), (b) (6)            | 22 Mar 2021 05:51:18 |
| Query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' answered with 'CP LOG LINE 2' (Site from DM). | Colleen McLellan (b) (4)    | 19 Mar 2021 18:03:59 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4)    | 19 Mar 2021 18:03:46 |
| Signature has been broken.   | Colleen McLellan (b) (4)    | 19 Mar 2021 18:03:46 |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE' reason for change: Data Entry Error  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:03:46 |
| User opened query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' (Site from DM).                   | (b) (4), (b) (6)            | 10 Mar 2021 09:29:49 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 22:16:27 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit                                | User                     | Time (GMT)           |
|--------------------------------------|--------------------------|----------------------|
| User entered 'STENT GRAFT PLACEMENT' | Colleen McLellan (b) (4) | 22 Feb 2021 20:32:00 |
|                                      | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '29.01'      | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'ug (ug)'    | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:22 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:22 |
| User entered empty. | System           | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:22 |
| User entered empty. | System           | 22 Feb 2021 20:32:00 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:22 |
| User entered empty. | System           | 22 Feb 2021 20:32:00 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User  | Time (GMT)                                   |
|---|---|--|
| Data hard locked.   | (b) (4), (b) (6)                              | 02 May 2021 09:48:29                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CARDIAC<br>THERAPY, ATC: CARDIAC STIMULANTS<br>EXCL. CARDIAC GLYCOSIDES, ATC:<br>ADRENERGIC AND DOPAMINERGIC AGENTS,<br>PRODUCT: PHENYLEPHRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 09 Apr 2021 06:20:35                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)               | 09 Apr 2021 06:20:35                         |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)            | 08 Apr 2021 23:59:42                         |
| DataPoint Verified.   | (b) (4), (b) (6)                              | 07 Apr 2021 21:34:48                         |
| Data point term sent to Coder<br>Coding entries removed.  | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:17:44<br>07 Apr 2021 19:17:10 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CARDIAC<br>THERAPY, ATC: CARDIAC STIMULANTS<br>EXCL. CARDIAC GLYCOSIDES, ATC:<br>ADRENERGIC AND DOPAMINERGIC AGENTS,<br>PRODUCT: PHENYLEPHRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 24 Mar 2021 10:52:31                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)               | 24 Mar 2021 10:52:31                         |
| Data point term sent to Coder<br>DataPoint Un-verified.   | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 23 Mar 2021 20:21:38<br>23 Mar 2021 20:20:58 |
| Signature has been broken.  | Colleen McLellan (b) (4)<br>(b) (4)           | 23 Mar 2021 20:20:58                         |
| User entered 'Phenylephrine 40 mg in Sodium<br>Chloride 0.9% 250 mL IV Soln' reason for change:<br>Data Entry Error   | Colleen McLellan (b) (4)<br>(b) (4)           | 23 Mar 2021 20:20:58                         |
| Data point term sent to Coder<br>Coding entries removed.  | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 18:04:48<br>19 Mar 2021 18:04:20 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CARDIAC<br>THERAPY, ATC: CARDIAC STIMULANTS<br>EXCL. CARDIAC GLYCOSIDES, ATC:<br>ADRENERGIC AND DOPAMINERGIC AGENTS,<br>PRODUCT: PHENYLEPHRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)     | 19 Mar 2021 11:35:31 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)     | 19 Mar 2021 11:35:31 |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4), (b) (6)<br>(b) (4)         | 26 Feb 2021 22:16:27 |
| Data point term sent to Coder   | System                              | 22 Feb 2021 20:35:58 |
| User entered 'Phenylephrine'  | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF<br>BILATERAL LEGS WITH INTERMITTENT<br>CLAUDICATION' reason for change: Data Entry<br>Error | Colleen McLellan (b) (4)            | 07 Apr 2021 19:17:10 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4)            | 19 Mar 2021 18:04:20 |
| Signature has been broken.   | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:04:20 |
| User entered 'AORTO-LEFT UNI-ILIAC<br>OCCLUSIVE DISEASE' reason for change: Data<br>Entry Error                              | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:04:20 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'STENT GRAFT PLACEMENT'   | Colleen McLellan (b) (4)            | 22 Feb 2021 20:35:34 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:16:22

[Dose per administration](#)

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                   | 02 May 2021 09:48:29 |
| DataPoint Verified.  | (b) (4)                            | 20 Apr 2021 19:14:32 |
| User signature succeeded.  | Stephen Spector (b) (4)            | 19 Apr 2021 18:05:13 |
| User closed query 'Per CDM Re-query:<br>Acknowledged, however previous query was not asking site to remove the decimal. Kindly review if the comma should be removed, as this is required per CCGs (eg. 3341) . Please also review if the decimal should be added back. Thank you.       | (b) (4)<br>(b) (4), (b) (6)        | 15 Apr 2021 06:59:26 |
| ' (Site from DM).<br>Query 'Per CDM Re-query: Acknowledged, however previous query was not asking site to remove the decimal. Kindly review if the comma should be removed, as this is required per CCGs (eg. 3341) . Please also review if the decimal should be added back. Thank you. | Megan Loughran (b) (4)<br>(b) (4)  | 13 Apr 2021 21:27:48 |
| ' answered with 'comma removed, decimal point added back. ' (Site from DM).<br>DataPoint Un-verified.  | Megan Loughran (b) (4)<br>(b) (4)  | 13 Apr 2021 21:27:33 |
| Signature has been broken.   | Megan Loughran (b) (4)<br>(b) (4)  | 13 Apr 2021 21:27:33 |
| User entered '3341.67' reason for change: Data Entry Error   | Megan Loughran (b) (4)<br>(b) (4)  | 13 Apr 2021 21:27:33 |
| User opened query 'Per CDM Re-query:<br>Acknowledged, however previous query was not asking site to remove the decimal. Kindly review if the comma should be removed, as this is required per CCGs (eg. 3341) . Please also review if the decimal should be added back. Thank you.       | (b) (4), (b) (6)                   | 09 Apr 2021 15:20:14 |
| ' (Site from DM).<br>User closed query 'Per CDM: Please note that, per CCGs, no period or a space should be used as a separator when entering large numbers. Kindly update as appropriate. ' (Site from DM).   | (b) (4)                            | 09 Apr 2021 15:20:14 |
| User signature succeeded.  | Stephen Spector (b) (4)<br>(b) (4) | 08 Apr 2021 23:59:42 |

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:16:22

[Dose per administration](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| Query 'Per CDM: Please note that, per CCGs, no period or a space should be used as a separator when entering large numbers. Kindly update as appropriate. ' answered with 'decimal removed, number rounded down per query request' (Site from DM).  | Colleen McLellan (b) (4) | 07 Apr 2021 19:03:56 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4) | 07 Apr 2021 19:03:52 |
| Signature has been broken.  | Colleen McLellan (b) (4) | 07 Apr 2021 19:03:52 |
| User entered '3,341' reason for change: Data Entry Error  | Colleen McLellan (b) (4) | 07 Apr 2021 19:03:52 |
| User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate or confirm the indicated dose.' (Site from DM).   | (b) (4), (b) (6)         | 25 Mar 2021 13:10:52 |
| User opened query 'Per CDM: Please note that, per CCGs, no period or a space should be used as a separator when entering large numbers. Kindly update as appropriate.' (Site from DM).  |                          | 25 Mar 2021 13:10:43 |
| Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate or confirm the indicated dose.' answered with 'dose confirmed in medical records - 3,341.67 ug given. No rationale from anesthesiologist provided in medical records . See medical records provided.' (Site from DM). | Colleen McLellan (b) (4) | 23 Mar 2021 20:20:47 |
| User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate or confirm the indicated dose.' (Site from DM).   | (b) (4), (b) (6)         | 10 Mar 2021 09:30:01 |
| User signature succeeded.   | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:16:22

[Dose per administration](#)

| Audit                   | User                     | Time (GMT)           |
|-------------------------|--------------------------|----------------------|
| User entered '3,341.67' | Colleen McLellan (b) (4) | 22 Feb 2021 20:35:34 |
|                         | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'ug (ug)'    | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:16:22

If dose unit is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:16:22

If route of administration is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:29 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:35:34 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:29 |
| User entered empty. | System           | 22 Feb 2021 20:35:34 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:29 |
| User entered empty. | System           | 22 Feb 2021 20:35:34 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:29 |
| User entered empty. | System           | 22 Feb 2021 20:35:34 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                               | Time (GMT)                                   |
|---|------------------------------------|--|
| Data hard locked.   | (b) (4), (b) (6)                   | 02 May 2021 09:48:33                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CARDIAC<br>THERAPY, ATC: VASODILATORS USED IN<br>CARDIAC DISEASES, ATC: ORGANIC<br>NITRATES, PRODUCT: GLYCERYL<br>TRINITRATE, PRODUCTSYNONYM:<br>NITROGLYCERIN - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 09:54:40                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 09:54:40                         |
| Data point term sent to Coder<br>Coding entries removed.  | System<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:17:40<br>07 Apr 2021 19:17:01 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CARDIAC<br>THERAPY, ATC: VASODILATORS USED IN<br>CARDIAC DISEASES, ATC: ORGANIC<br>NITRATES, PRODUCT: GLYCERYL<br>TRINITRATE, PRODUCTSYNONYM:<br>NITROGLYCERIN - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 24 Mar 2021 05:24:25                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 24 Mar 2021 05:24:25                         |
| Data point term sent to Coder<br>Coding entries removed.  | System<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:04:48<br>19 Mar 2021 18:04:43 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CARDIAC<br>THERAPY, ATC: VASODILATORS USED IN<br>CARDIAC DISEASES, ATC: ORGANIC<br>NITRATES, PRODUCT: GLYCERYL<br>TRINITRATE, PRODUCTSYNONYM:<br>NITROGLYCERIN - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 17 Mar 2021 12:03:50                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 17 Mar 2021 12:03:50                         |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Name of Medication](#)

| Audit                         | User                     | Time (GMT)           |
|-------------------------------|--------------------------|----------------------|
| User signature succeeded.     | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.           | (b) (4)                  |                      |
|                               | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| Data point term sent to Coder | System                   | 22 Feb 2021 20:36:59 |
| User entered 'NITROGLYCERIN'  | Colleen McLellan (b) (4) | 22 Feb 2021 20:36:23 |
|                               | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF<br>BILATERAL LEGS WITH INTERMITTENT<br>CLAUDICATION' reason for change: Data Entry<br>Error | Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:17:01 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 18:04:43 |
| Signature has been broken.   | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 18:04:43 |
| User entered 'AORTO-LEFT UNI-ILIAC<br>OCCLUSIVE DISEASE' reason for change: Data<br>Entry Error                              | Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 18:04:43 |
| User signature succeeded.  | Stephen Spector (b) (4)<br>(b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4), (b) (6)                    | 26 Feb 2021 22:16:27 |
| User entered 'STENT GRAFT PLACEMENT'   | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '500'        | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'ug (ug)'    | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:33 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:33 |
| User entered empty. | System           | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:33 |
| User entered empty. | System           | 22 Feb 2021 20:36:23 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:33 |
| User entered empty. | System           | 22 Feb 2021 20:36:23 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                               | Time (GMT)                                   |
|---|------------------------------------|--|
| Data hard locked.   | (b) (4), (b) (6)                   | 02 May 2021 09:48:44                         |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 06:30:41                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 06:30:41                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:17:39<br>07 Apr 2021 19:16:51 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 30 Mar 2021 14:29:32                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 30 Mar 2021 14:29:32                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:05:49<br>19 Mar 2021 18:04:51 |
| User signature succeeded.   | (b) (4)<br>Stephen Spector (b) (4) | 06 Mar 2021 01:50:28                         |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 02 Mar 2021 08:04:37                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 02 Mar 2021 08:04:37                         |
| DataPoint Verified.   | (b) (4), (b) (6)                   | 26 Feb 2021 22:16:27                         |
| Data point term sent to Coder User entered 'HEPARIN'  | System<br>Colleen McLellan (b) (4) | 22 Feb 2021 20:38:01<br>22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 02 May 2021 09:48:44 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 08 Apr 2021 23:59:42 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION' reason for change: Data Entry Error | Colleen McLellan (b) (4)    | 07 Apr 2021 19:16:51 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:04:51 |
| Signature has been broken.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:04:51 |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE' reason for change: Data Entry Error                           | Colleen McLellan (b) (4)    | 19 Mar 2021 18:04:51 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 22:16:27 |
| User entered 'STENT GRAFT PLACEMENT'  | Colleen McLellan (b) (4)    | 22 Feb 2021 20:37:15 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '7000'       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded.    | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Other (OTHER)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'UNITS'      | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:44 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:44 |
| User entered empty. | System           | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:44 |
| User entered empty. | System           | 22 Feb 2021 20:37:15 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:44 |
| User entered empty. | System           | 22 Feb 2021 20:37:15 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                               | Time (GMT)                                   |
|---|------------------------------------|--|
| Data hard locked.   | (b) (4), (b) (6)                   | 02 May 2021 09:48:47                         |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 09:34:49                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 08 Apr 2021 09:34:49                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 07 Apr 2021 19:17:40<br>07 Apr 2021 19:16:42 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 24 Mar 2021 06:42:28                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 24 Mar 2021 06:42:28                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:05:49<br>19 Mar 2021 18:05:06 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 15 Mar 2021 08:05:53                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 15 Mar 2021 08:05:53                         |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4) | 06 Mar 2021 01:50:28                         |
| DataPoint Verified.   | (b) (4), (b) (6)                   | 26 Feb 2021 22:16:27                         |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Name of Medication](#)

| Audit                         | User                     | Time (GMT)           |
|-------------------------------|--------------------------|----------------------|
| Data point term sent to Coder | System                   | 22 Feb 2021 20:39:02 |
| User entered 'ONDANSETRON'    | Colleen McLellan (b) (4) | 22 Feb 2021 20:38:06 |
|                               | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 02 May 2021 09:48:47 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 08 Apr 2021 23:59:42 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION' reason for change: Data Entry Error | Colleen McLellan (b) (4)    | 07 Apr 2021 19:16:42 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:05:06 |
| Signature has been broken.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:05:06 |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE' reason for change: Data Entry Error                           | Colleen McLellan (b) (4)    | 19 Mar 2021 18:05:06 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 22:16:27 |
| User entered 'STENT GRAFT PLACEMENT'  | Colleen McLellan (b) (4)    | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '4'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'mg (mg)'    | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:47 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:47 |
| User entered empty. | System           | 22 Feb 2021 20:38:06 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:47 |
| User entered empty. | System           | 22 Feb 2021 20:38:06 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:47 |
| User entered empty. | System           | 22 Feb 2021 20:38:06 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User  | Time (GMT)                                   |
|---|---|--|
| Data hard locked.   | (b) (4), (b) (6)                              | 02 May 2021 09:48:52                         |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 07 Apr 2021 19:17:42                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)               | 07 Apr 2021 19:17:42                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 07 Apr 2021 19:16:38<br>07 Apr 2021 19:16:30 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 19 Mar 2021 18:06:34                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)               | 19 Mar 2021 18:06:34                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Colleen McLellan (b) (4)<br>(b) (4) | 19 Mar 2021 18:05:49<br>19 Mar 2021 18:05:15 |
| User signature succeeded.   | Stephen Spector (b) (4)<br>(b) (4)            | 06 Mar 2021 01:50:28                         |
| DataPoint Verified.   | (b) (4), (b) (6)                              | 26 Feb 2021 22:16:27                         |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 22 Feb 2021 20:42:15 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)     | 22 Feb 2021 20:42:15 |
| Data point term sent to Coder   | System                   | 22 Feb 2021 20:41:07 |
| User entered 'LACTATED RINGERS'   | Colleen McLellan (b) (4) | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 02 May 2021 09:48:52 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 08 Apr 2021 23:59:42 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF BILATERAL LEGS WITH INTERMITTENT CLAUDICATION' reason for change: Data Entry Error | Colleen McLellan (b) (4)    | 07 Apr 2021 19:16:30 |
| DataPoint Un-verified.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:05:15 |
| Signature has been broken.  | Colleen McLellan (b) (4)    | 19 Mar 2021 18:05:15 |
| User entered 'AORTO-LEFT UNI-ILIAC OCCLUSIVE DISEASE' reason for change: Data Entry Error                           | Colleen McLellan (b) (4)    | 19 Mar 2021 18:05:15 |
| User signature succeeded.   | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 22:16:27 |
| User entered 'STENT GRAFT PLACEMENT'  | Colleen McLellan (b) (4)    | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '507.5'      | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'mL (mL)'    | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:16:22

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:52 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:52 |
| User entered empty. | System           | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:52 |
| User entered empty. | System           | 22 Feb 2021 20:40:27 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:52 |
| User entered empty. | System           | 22 Feb 2021 20:40:27 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 09:48:56 |
| User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: SUGAMMADEX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 08 Apr 2021 09:50:43 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | (b) (4)                  |                      |
| Data point term sent to Coder   | System                   | 07 Apr 2021 19:16:37 |
| Coding entries removed.   | Colleen McLellan (b) (4) | 07 Apr 2021 19:16:17 |
| User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: SUGAMMADEX - version WHODrug-Global-B3\\202003. | (b) (4)                  |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)     | 24 Mar 2021 13:58:34 |
| Data point term sent to Coder   | (b) (4)                  |                      |
| Coding entries removed.   | System                   | 19 Mar 2021 18:05:50 |
| User signature succeeded.   | Colleen McLellan (b) (4) | 19 Mar 2021 18:05:23 |
| User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: SUGAMMADEX - version WHODrug-Global-B3\\202003. | (b) (4)                  |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Stephen Spector (b) (4)  | 06 Mar 2021 01:50:28 |
| DataPoint Verified.   | (b) (4)                  |                      |
| Data point term sent to Coder   | Coder Import (b) (4)     | 04 Mar 2021 23:51:52 |
| User entered 'SUGAMMADEX'   | (b) (4)                  |                      |
|   | Coder Import (b) (4)     | 04 Mar 2021 23:51:52 |
|   | (b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
|   | System                   | 22 Feb 2021 20:42:14 |
|   | Colleen McLellan (b) (4) | 22 Feb 2021 20:41:16 |
|   | (b) (4)                  |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 07 Apr 2021 21:34:48 |
| User entered 'ATHEROSCLEROSIS OF<br>BILATERAL LEGS WITH INTERMITTENT<br>CLAUDICATION' reason for change: Data Entry<br>Error | Colleen McLellan (b) (4)            | 07 Apr 2021 19:16:17 |
| DataPoint Un-verified.   | Colleen McLellan (b) (4)            | 19 Mar 2021 18:05:23 |
| Signature has been broken.   | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:05:23 |
| User entered 'AORTO-LEFT UNI-ILIAC<br>OCCLUSIVE DISEASE' reason for change: Data<br>Entry Error                              | (b) (4)<br>Colleen McLellan (b) (4) | 19 Mar 2021 18:05:23 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'STENT GRAFT PLACEMENT'   | Colleen McLellan (b) (4)            | 22 Feb 2021 20:41:16 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '130'        | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'mg (mg)'    | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'once (ONCE)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded.                | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'Intravenous (INTRAVENOUS)' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[If route of administration is Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered empty.       | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '0'          | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded.  | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered '16 Feb 2021' | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 09:48:56 |
| User signature succeeded. | Stephen Spector (b) (4)             | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)         | 26 Feb 2021 22:16:27 |
| User entered 'No (N)'     | Colleen McLellan (b) (4)<br>(b) (4) | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:56 |
| User entered empty. | System           | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:56 |
| User entered empty. | System           | 22 Feb 2021 20:41:16 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:48:56 |
| User entered empty. | System           | 22 Feb 2021 20:41:16 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 02 May 2021 09:48:59 |
| User signature succeeded.   | Stephen Spector (b) (4)         | 08 Apr 2021 23:59:42 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 07 Apr 2021 21:34:48 |
| User coded data point as ATC: ANTIINFECTIVES<br>FOR SYSTEMIC USE, ATC: ANTIBACTERIALS<br>FOR SYSTEMIC USE, ATC: TETRACYCLINES,<br>ATC: TETRACYCLINES, PRODUCT:<br>DOXYCYCLINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 19 Mar 2021 07:49:53 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 19 Mar 2021 07:49:53 |
| Data point term sent to Coder   | System                          | 18 Mar 2021 17:47:26 |
| User entered 'Doxycycline'  | (b) (4), (b) (6)                | 18 Mar 2021 17:46:38 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded. | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered 'No (N)'     |                         | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.                                       | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded.                               | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.                                     | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered 'LEFT INNER THIGH SURGICAL SITE INFECTION' |                         | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded. | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered '100'        |                         | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded. | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered 'mg (mg)'    |                         | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded. | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered empty.       |                         | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded.        | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.              | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered 'twice daily (BID)' |                         | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 09:48:59 |
| User signature succeeded. | Stephen Spector (b) (4)     | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 21:34:48 |
| User entered empty.       |                             | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded.  | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.        | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered 'Oral (ORAL)' |                         | 18 Mar 2021 17:46:38 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded. | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered empty.       |                         | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded. | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered '1 Mar 2021' |                         | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded. | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered '0'          |                         | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded. | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered 'No (N)'     |                         | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded.  | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.        | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered '15 Mar 2021' |                         | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 09:48:59 |
| User signature succeeded. | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered 'No (N)'     |                         | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 09:48:59 |
| User entered '2'  | System           | 18 Mar 2021 17:46:38 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 09:48:59 |
| User entered '1'  | System           | 18 Mar 2021 17:46:38 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 09:48:59 |
| User entered '804 (804)' | System           | 18 Mar 2021 17:46:38 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.  | (b) (4)                           |                      |
|  | (b) (4), (b) (6)                  | 07 Apr 2021 21:34:48 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC:<br>DIURETICS, ATC: POTASSIUM-SPARING<br>AGENTS, ATC: ALDOSTERONE<br>ANTAGONISTS, PRODUCT:<br>SPIRONOLACTONE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 05 Apr 2021 19:19:51 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)   | 05 Apr 2021 19:19:51 |
| Data point term sent to Coder  | System                            | 05 Apr 2021 19:17:41 |
| User entered 'spironolactone'  | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                       | User                              | Time (GMT)           |
|-----------------------------|-----------------------------------|----------------------|
| User signature succeeded.   | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.         | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered 'hypertension' | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered '50'         | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered 'mg (mg)'    | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded.      | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered 'once daily (QD)' | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:16:22

If frequency is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered 'Oral (ORAL)' | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded.  | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered '20 Jan 2021' | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 07 Apr 2021 21:34:48 |
| User entered '0'          | Megan Loughran (b) (4)  | 05 Apr 2021 19:16:50 |
|                           | (b) (4)                 |                      |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered 'Yes (Y)'    | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered empty.       | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)           | 08 Apr 2021 23:59:42 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 07 Apr 2021 21:34:48 |
| User entered 'No (N)'     | Megan Loughran (b) (4)<br>(b) (4) | 05 Apr 2021 19:16:50 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 19:16:50 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Apr 2021 19:16:50 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                | 20 Apr 2021 19:14:32 |
| User signature succeeded.   | Stephen Spector (b) (4)         | 19 Apr 2021 18:05:13 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 14 Apr 2021 10:48:55 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 14 Apr 2021 10:48:55 |
| Data point term sent to Coder   | System                          | 12 Apr 2021 22:31:44 |
| User entered 'GABAPENTIN'   | Nancy Tang (b) (4)              | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'No (N)'     | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded.                      | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'BILATERAL LOWER LEG<br>TINGLING' | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '100'        | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'mg (mg)'    | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

If dose unit is Other, specify

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                                  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded.              | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'three times daily (TID)' | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded.  | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

If route of administration is Other, specify

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded.  | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '12 Apr 2021' | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'No (N)'     | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Apr 2021 22:31:19 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Apr 2021 22:31:19 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:16:22

Name of Medication

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                   | 20 Apr 2021 19:14:32 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 20 Apr 2021 13:16:04 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)    | 20 Apr 2021 13:16:04 |
| Data point term sent to Coder  | System                             | 19 Apr 2021 20:28:21 |
| Coding entries removed.  | Megan Loughran (b) (4)<br>(b) (4)  | 19 Apr 2021 20:28:00 |
| User signature succeeded.  | Stephen Spector (b) (4)<br>(b) (4) | 19 Apr 2021 18:05:13 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 12 Apr 2021 23:06:17 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)    | 12 Apr 2021 23:06:17 |
| Data point term sent to Coder  | System                             | 12 Apr 2021 22:33:46 |
| User entered 'Vitamin B12'   | Nancy Tang (b) (4)<br>(b) (4)      | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User signature succeeded.                       | Stephen Spector (b) (4) | 23 Apr 2021 20:51:21 |
| DataPoint Verified.                             | (b) (4)                 |                      |
|   | (b) (4), (b) (6)        | 20 Apr 2021 19:14:32 |
| Signature has been broken.                      | Megan Loughran (b) (4)  | 19 Apr 2021 20:28:00 |
|   | (b) (4)                 |                      |
| User entered 'prophylaxis for VITAMIN B12       | Megan Loughran (b) (4)  | 19 Apr 2021 20:28:00 |
| DEFICIENCY' reason for change: Data Entry Error | (b) (4)                 |                      |
| User signature succeeded.                       | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
|   | (b) (4)                 |                      |
| User entered 'Vitamin B12 Deficiency'           | Nancy Tang (b) (4)      | 12 Apr 2021 22:32:45 |
|   |                         |                      |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '1000'       | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'mg (mg)'    | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[If dose unit is Other, specify](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[Frequency](#)

| Audit                        | User                          | Time (GMT)           |
|------------------------------|-------------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded.    | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'other (OTHER)' | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                       | User                          | Time (GMT)           |
|-----------------------------|-------------------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded.   | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Twice a week' | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded.  | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:16:22

If route of administration is Other, specify

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded.  | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '01 Mar 2021' | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered '0'          | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)       | 19 Apr 2021 18:05:13 |
| User entered 'No (N)'     | (b) (4)<br>Nancy Tang (b) (4) | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Apr 2021 22:32:45 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Apr 2021 22:32:45 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:16:22

[Name of Medication](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded.  | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 16 Apr 2021 01:05:12 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)     | 16 Apr 2021 01:05:12 |
| Data point term sent to Coder  | System                   | 15 Apr 2021 21:26:31 |
| User entered 'IBUPROFEN'   | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered 'No (N)'     | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded.          | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered 'PIRIFORMIS SYNDROME' | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered '600'        | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered 'mg (mg)'    | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:16:22

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered empty.       | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:16:22

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded.      | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered 'as needed (PRN)' | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[If frequency is Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered empty.       | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded.  | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered 'Oral (ORAL)' | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |



US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:16:22

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered empty.       | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded.  | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered '21 Oct 2020' | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered '0'          | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered 'Yes (Y)'    | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

US3642217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:16:22

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered empty.       | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 19:14:32 |
| User signature succeeded. | Stephen Spector (b) (4)  | 19 Apr 2021 18:05:13 |
| User entered 'No (N)'     | Colleen McLellan (b) (4) | 15 Apr 2021 21:26:09 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Apr 2021 21:26:09 |

**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Apr 2021 21:26:09 |



**US3642217**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:16:22**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Apr 2021 21:26:09 |

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:16:22

[Were any concomitant procedures performed?](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 03 May 2021 09:14:10 |
| DataPoint Verified.  | (b) (4)                 | 07 Apr 2021 21:36:37 |
| User signature succeeded.                                  | Stephen Spector (b) (4) | 13 Mar 2021 02:20:57 |
| DataPoint Un-verified.                                     | (b) (4)                 |                      |
|  | Nancy Tang (b) (4)      | 11 Mar 2021 19:22:44 |
| Signature has been broken.                                 | (b) (4)                 |                      |
|  | Nancy Tang (b) (4)      | 11 Mar 2021 19:22:44 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4)                 |                      |
|  | Nancy Tang (b) (4)      | 11 Mar 2021 19:22:44 |
| DataPoint Verified.  | (b) (4), (b) (6)        | 25 Feb 2021 21:38:23 |
|  | (b) (4)                 |                      |
| User signature succeeded.                                  | Stephen Spector (b) (4) | 13 Feb 2021 17:54:30 |
|  | (b) (4)                 |                      |
| User entered 'No (N)'                                      | Son Do (b) (4)          | 17 Sep 2020 16:24:02 |

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:16:22

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 07 Apr 2021 21:36:42 |
| User signature succeeded.  | Stephen Spector (b) (4)       | 20 Mar 2021 00:00:35 |
| User entered '31 Dec 2020' | (b) (4)<br>Nancy Tang (b) (4) | 15 Mar 2021 22:57:23 |

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:16:22

[Procedure/Surgery](#)

| Audit                           | User                          | Time (GMT)           |
|---------------------------------|-------------------------------|----------------------|
| DataPoint Verified.             | (b) (4), (b) (6)              | 07 Apr 2021 21:36:42 |
| User signature succeeded.       | Stephen Spector (b) (4)       | 20 Mar 2021 00:00:35 |
| User entered 'MRI OF LOWER LEG' | (b) (4)<br>Nancy Tang (b) (4) | 15 Mar 2021 22:57:23 |

**US3642217**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                             | User                          | Time (GMT)           |
|-----------------------------------|-------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)              | 07 Apr 2021 21:36:42 |
| User signature succeeded.         | Stephen Spector (b) (4)       | 20 Mar 2021 00:00:35 |
| User entered 'Adverse Event (AE)' | (b) (4)<br>Nancy Tang (b) (4) | 15 Mar 2021 22:57:23 |

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:16:22

If indication is Other, specify

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 07 Apr 2021 21:36:42 |
| User signature succeeded. | Stephen Spector (b) (4)       | 20 Mar 2021 00:00:35 |
| User entered empty.       | (b) (4)<br>Nancy Tang (b) (4) | 15 Mar 2021 22:57:23 |

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:16:22

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 May 2021 01:34:58 |
| DataPoint Verified.        |                             | 07 Apr 2021 21:36:42 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered '16 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:53:16 |

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:16:22

[Procedure/Surgery](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)            | 03 May 2021 01:34:58 |
| DataPoint Verified.                                |                             | 07 Apr 2021 21:36:42 |
| User signature succeeded.                          | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'ANGIOPLASTY WITH STENT<br>INSERTION' | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:53:16 |



**US3642217**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Indication](#)

| Audit                               | User                        | Time (GMT)           |
|-------------------------------------|-----------------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6)            | 03 May 2021 01:34:58 |
| DataPoint Verified.                 |                             | 07 Apr 2021 21:36:42 |
| User signature succeeded.           | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered 'Medical History (MH)' | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:53:16 |

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:16:22

If indication is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 May 2021 01:34:58 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:42 |
| User signature succeeded. | Stephen Spector (b) (4)     | 20 Mar 2021 00:00:35 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 17:53:16 |

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:16:22

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 May 2021 01:35:02 |
| DataPoint Verified.        |                             | 29 Apr 2021 19:40:47 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 23 Apr 2021 20:51:21 |
| User entered '01 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 22 Apr 2021 18:08:19 |

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:16:22

[Procedure/Surgery](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 May 2021 01:35:02 |
| DataPoint Verified.        |                             | 29 Apr 2021 19:40:47 |
| User signature succeeded.  | Stephen Spector (b) (4)     | 23 Apr 2021 20:51:21 |
| User entered 'MRI of back' | (b) (4)<br>(b) (4), (b) (6) | 22 Apr 2021 18:08:19 |

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:16:22

[Indication](#)

| Audit                               | User                        | Time (GMT)           |
|-------------------------------------|-----------------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6)            | 03 May 2021 01:35:02 |
| DataPoint Verified.                 |                             | 29 Apr 2021 19:40:47 |
| User signature succeeded.           | Stephen Spector (b) (4)     | 23 Apr 2021 20:51:21 |
| User entered 'Medical History (MH)' | (b) (4)<br>(b) (4), (b) (6) | 22 Apr 2021 18:08:19 |

US3642217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:16:22

If indication is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 May 2021 01:35:02 |
| DataPoint Verified.       |                             | 29 Apr 2021 19:40:47 |
| User signature succeeded. | Stephen Spector (b) (4)     | 23 Apr 2021 20:51:21 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Apr 2021 18:08:19 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User signature succeeded.                             | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                                   | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered<br>'USA-US109-2021-MRNA-1273-P301000006' | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |



**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     |                         | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Stephen'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's Last Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Spector'    |                         | 22 Feb 2021 16:56:38 |



**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator Country](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 19:35:44 |
| User entered 'US'         | System                  | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 14 Apr 2021 13:27:41 |
| User entered '5' | System | 08 Apr 2021 16:09:19 |
| User entered '4' | System | 22 Mar 2021 17:49:53 |
| User entered '3' | System | 22 Feb 2021 20:19:03 |
| User entered '2' | System | 22 Feb 2021 19:36:24 |
| User entered '1' | System | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User signature succeeded.                             | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                                   | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered<br>'USA-US109-2021-MRNA-1273-P301000006' | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |



**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Stephen'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's Last Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Spector'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Feb 2021 19:35:44 |
| User entered 'US'         | System                      | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 14 Apr 2021 13:27:41 |
| User entered '5' | System | 08 Apr 2021 16:09:19 |
| User entered '4' | System | 22 Mar 2021 17:49:53 |
| User entered '3' | System | 22 Feb 2021 20:19:03 |
| User entered '2' | System | 22 Feb 2021 19:36:24 |
| User entered '1' | System | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:16:22**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:37:40 |
| User entered '22/Feb/2021 11:57' | System                      | 22 Feb 2021 16:57:40 |

US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:16:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 19:35:44 |
| User entered 'I'          |                         | 22 Feb 2021 16:57:40 |



**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User signature succeeded.                             | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                                   | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered<br>'USA-US109-2021-MRNA-1273-P301000006' | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                      | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                      | 22 Feb 2021 16:56:38 |



**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'Stephen'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's Last Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Spector'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator Country](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 19:35:44 |
| User entered 'US'         | System                  | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 14 Apr 2021 13:27:41 |
| User entered '5' | System | 08 Apr 2021 16:09:19 |
| User entered '4' | System | 22 Mar 2021 17:49:53 |
| User entered '3' | System | 22 Feb 2021 20:19:03 |
| User entered '2' | System | 22 Feb 2021 19:36:24 |
| User entered '1' | System | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:16:22**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:37:40 |
| User entered '22/Feb/2021 14:36' | System                      | 22 Feb 2021 19:36:24 |

US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:16:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 20:18:41 |
| User entered 'I'          |                         | 22 Feb 2021 19:36:24 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User signature succeeded.                             | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.                                  |                         | 22 Feb 2021 16:57:19 |
| User entered<br>'USA-US109-2021-MRNA-1273-P301000006' | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |



**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Stephen'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's Last Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Spector'    | System                  | 22 Feb 2021 16:56:38 |



**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator Country](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 19:35:44 |
| User entered 'US'         | System                  | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 14 Apr 2021 13:27:41 |
| User entered '5' | System | 08 Apr 2021 16:09:19 |
| User entered '4' | System | 22 Mar 2021 17:49:53 |
| User entered '3' | System | 22 Feb 2021 20:19:03 |
| User entered '2' | System | 22 Feb 2021 19:36:24 |
| User entered '1' | System | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:16:22**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:37:40 |
| User entered '22/Feb/2021 15:19' | System                      | 22 Feb 2021 20:19:03 |

US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:16:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Mar 2021 17:49:27 |
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| User entered 'I'          |                         | 22 Feb 2021 20:19:03 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User signature succeeded.                             | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                                   | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered<br>'USA-US109-2021-MRNA-1273-P301000006' | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |



**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Stephen'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's Last Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Spector'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator Country](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 19:35:44 |
| User entered 'US'         | System                  | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 14 Apr 2021 13:27:41 |
| User entered '5' | System | 08 Apr 2021 16:09:19 |
| User entered '4' | System | 22 Mar 2021 17:49:53 |
| User entered '3' | System | 22 Feb 2021 20:19:03 |
| User entered '2' | System | 22 Feb 2021 19:36:24 |
| User entered '1' | System | 22 Feb 2021 16:57:40 |



**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:16:22**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)        | 07 Apr 2021 21:36:19 |
| User signature succeeded.        | Stephen Spector (b) (4) | 26 Mar 2021 21:20:00 |
| User entered '22/Mar/2021 13:49' | (b) (4)<br>System       | 22 Mar 2021 17:49:53 |

US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:16:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 08 Apr 2021 16:08:52 |
| DataPoint Verified.       |                             | 07 Apr 2021 21:36:19 |
| User signature succeeded. | Stephen Spector (b) (4)     | 26 Mar 2021 21:20:00 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 22 Mar 2021 17:49:53 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User signature succeeded.                             | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.                                  |                         | 22 Feb 2021 16:57:19 |
| User entered<br>'USA-US109-2021-MRNA-1273-P301000006' | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |



**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Stephen'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Feb 2021 16:57:19 |
| User entered 'Spector'    | System                      | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4)     | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Feb 2021 19:35:44 |
| User entered 'US'         | System                      | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 14 Apr 2021 13:27:41 |
| User entered '5' | System | 08 Apr 2021 16:09:19 |
| User entered '4' | System | 22 Mar 2021 17:49:53 |
| User entered '3' | System | 22 Feb 2021 20:19:03 |
| User entered '2' | System | 22 Feb 2021 19:36:24 |
| User entered '1' | System | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:16:22**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)        | 20 Apr 2021 15:23:53 |
| User signature succeeded.        | Stephen Spector (b) (4) | 08 Apr 2021 23:59:42 |
| User entered '08/Apr/2021 12:09' | (b) (4)<br>System       | 08 Apr 2021 16:09:19 |

US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:16:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 15:23:53 |
| Reviewed for Safety.      |                             | 14 Apr 2021 13:27:17 |
| User signature succeeded. | Stephen Spector (b) (4)     | 08 Apr 2021 23:59:42 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:09:19 |



**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User signature succeeded.                             | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.                                  |                         | 22 Feb 2021 16:57:19 |
| User entered<br>'USA-US109-2021-MRNA-1273-P301000006' | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 16:57:19 |
| User entered 'Yes (Y)'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'No (N)'     | System                  | 22 Feb 2021 16:56:38 |



**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Stephen'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator's Last Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4)                 | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 22 Feb 2021 16:57:19 |
| User entered 'Spector'    | System                  | 22 Feb 2021 16:56:38 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[Investigator Country](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Stephen Spector (b) (4) | 06 Mar 2021 01:50:28 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 25 Feb 2021 21:37:40 |
| Reviewed for Safety.      |                         | 22 Feb 2021 19:35:44 |
| User entered 'US'         | System                  | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:16:22**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 14 Apr 2021 13:27:41 |
| User entered '5' | System | 08 Apr 2021 16:09:19 |
| User entered '4' | System | 22 Mar 2021 17:49:53 |
| User entered '3' | System | 22 Feb 2021 20:19:03 |
| User entered '2' | System | 22 Feb 2021 19:36:24 |
| User entered '1' | System | 22 Feb 2021 16:57:40 |

**US3642217**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:16:22**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)        | 20 Apr 2021 15:23:53 |
| User signature succeeded.        | Stephen Spector (b) (4) | 19 Apr 2021 18:05:13 |
| User entered '14/Apr/2021 09:27' | (b) (4)<br>System       | 14 Apr 2021 13:27:41 |

US3642217

Folder: SAE USA-US109-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:16:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 15:23:53 |
| User signature succeeded. | Stephen Spector (b) (4)     | 19 Apr 2021 18:05:13 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 13:27:41 |