

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

|    |   |                 |
|----|---|-----------------|
| 1. | Select appropriate response - Protocol version                        | 24 JUL 2020     |
| 2. | Select appropriate response - What cohort does the subject belong to? | STAGE 3 COHORTS |

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Informed Consent**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Sep/16/2020 |
|----|--------------|--|

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [12231182]                                     |
| 2. | Birth Date:                     | (b) (6)/1936                                   |
| 3. | Sex:                            | MALE   |
| 4. | Ethnicity:                      | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE  |
| 6. | Racial Designation:             |  |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Sep/16/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

**Form Comments**

**Inclusion Criteria Not Met**

|    |  |                |
|----|--|----------------|
| 1. | Description of Inclusion Criterion Not Met | Not Applicable |
|----|--|----------------|

**Exclusion Criteria Met**

|    |  |                |
|----|--|----------------|
| 2. | Description of Exclusion Criterion Met | Not Applicable |
|----|--|----------------|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Disposition - Screening**

|    |  |             |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death | Sep/16/2020 |
| 2. | Phase of Disposition:                    | SCREENING   |
| 3. | Status:                                  | COMPLETED   |
| 4. | Specify Status:                          | [ ]         |

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Medical History Details**

|     |  |                                 |
|-----|--|---------------------------------|
| 1.a | Line/MH Number:  | [1]                             |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [dislocated shoulder]           |
|     | Start Date:  | UNK/UNK/1966                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/1967 |
| 1.b | Line/MH Number:  | [2]                             |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [atrial fibrillation]           |
|     | Start Date:  | UNK/UNK/1998                    |
|     | Ongoing:   | YES                             |
| 1.c | Line/MH Number:  | [3]                             |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [sleep apnea]                   |
|     | Start Date:  | UNK/UNK/2012                    |
|     | Ongoing:   | YES                             |
| 1.d | Line/MH Number:  | [4]                             |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [diverticulitis]                |
|     | Start Date:  | UNK/UNK/2019                    |
|     | Ongoing:   | YES                             |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

|     |  |                |
|-----|--|----------------|
| 1.e | Line/MH Number:  | [5]            |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Hypertension] |
|     | Start Date:  | UNK/UNK/2001   |
|     | Ongoing:   | YES            |

|     |  |                           |
|-----|--|---------------------------|
| 1.f | Line/MH Number:  | [6]                       |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [gastroesophageal reflux] |
|     | Start Date:  | UNK/UNK/2001              |
|     | Ongoing:   | YES                       |

|     |  |                         |
|-----|--|-------------------------|
| 1.g | Line/MH Number:  | [7]                     |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [barrett's Esophagitus] |
|     | Start Date:  | UNK/UNK/2017            |
|     | Ongoing:   | YES                     |

|     |  |                                |
|-----|--|--------------------------------|
| 1.h | Line/MH Number:  | [8]                            |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Benign Prostatic Hypertrophy] |
|     | Start Date:  | UNK/UNK/2017                   |
|     | Ongoing:   | YES                            |

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**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:56

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Vital Signs**

|    |                  |             |
|----|------------------|-------------|
| 1. | Date:            | Sep/16/2020 |
| 2. | Weight:          | [78.4]      |
| 3. | Unit:            | kg          |
| 4. | Height:          | [169.0]     |
| 5. | Unit:            | cm          |
| 6. | Body Mass Index: | [27.5]      |

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 7.a | Record Identifier:    | 1           |
|     | Temperature:          | [98.1]      |
|     | Unit:                 | F           |
|     | Temperature Location: | ORAL CAVITY |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** RANDOMIZATION

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Disposition**

|    |                       |             |
|----|-----------------------|-------------|
| 1. | Randomization Date :  | Sep/16/2020 |
| 2. | Randomization Number: | [260407]    |
| 3. | Randomization Group:  | [ ]         |

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Sep/16/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BPXXMJ] |
| 5.b | Sample ID | [BPXXMK] |
| 5.c | Sample ID | [BPXXML] |

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**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Sep/16/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BPXXMH] |
|-----|-----------|----------|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Vaccination**

|     |   |   |
|-----|---|---|
| 1.  | Was there a temporary delay of vaccination?   | NO  |
| 2.  | Treatment Name  | [BLINDED THERAPY]                         |
| 3.  | Formulation:  | INJECTION                                 |
| 4.  | Dose Date Time:   | Sep/16/2020 13:36                         |
| 5.  | Anatomical Location:  | DELTOID MUSCLE                            |
| 6.  | Body Side:  | LEFT                                      |
| 7.  | Route:  | INTRAMUSCULAR                             |
| 8.  | Actual Dose:  | [ ]                                       |
| 9.  | Unit:   |   |
| 10. | Timeframe Subject Was Observed  | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES                                       |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

|    |   |  |
|----|---|--|
| 1. | Select appropriate response - Reactogenicity diary collection | NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT |
|----|---|--|

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Oct/9/2020 |
| 2. | Erroneous Visit |            |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Vital Signs**

|    |       |            |
|----|-------|------------|
| 1. | Date: | Oct/9/2020 |
|----|-------|------------|

**Vital Signs Details**

|     |                       |          |
|-----|-----------------------|----------|
| 2.a | Record Identifier:    | 1        |
|     | Temperature:          | [97.8]   |
|     | Unit:                 | F        |
|     | Temperature Location: | FOREHEAD |



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE                                     |
| 2. | Sample Type  | NASAL_SWAB                               |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Oct/9/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                      |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BPW1NZ] |
|-----|-----------|----------|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

**eCRF Audit Trail History**

**Vaccination**

|     |   |   |
|-----|---|---|
| 1.  | Was there a temporary delay of vaccination?   | NO  |
| 2.  | Treatment Name  | [BLINDED THERAPY]                         |
| 3.  | Formulation:  | INJECTION                                 |
| 4.  | Dose Date Time:   | Oct/9/2020 11:03                          |
| 5.  | Anatomical Location:  | DELTOID MUSCLE                            |
| 6.  | Body Side:  | LEFT                                      |
| 7.  | Route:  | INTRAMUSCULAR                             |
| 8.  | Actual Dose:  | [ ]                                       |
| 9.  | Unit:   |   |
| 10. | Timeframe Subject Was Observed  | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES                                       |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Nov/6/2020 |
| 2. | Erroneous Visit |            |

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE                                     |
| 2. | Sample Type  | SERUM                                    |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Nov/6/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                      |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BPW1RD] |
| 5.b | Sample ID | [BPW1RF] |
| 5.c | Sample ID | [BPW1RG] |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)



**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**COVID-19 Illness Visit**

|    |                         |  |
|----|-------------------------|--|
| 3. | COVID-19 Illness Visit: |  |
|----|-------------------------|--|

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 28-Mar-2021 02:35

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Signs and Symptoms**

|    |                                |    |
|----|--------------------------------|----|
| 1. | Date of Assessment:            | // |
| 2. | Date of First Symptom Started: | // |
| 3. | Symptoms Ongoing?              |    |

**Symptoms**

|    |                      |  |
|----|----------------------|--|
| 4. | Symptoms:            |  |
|    | Was symptom present? |  |

**Symptoms - Other**

|    |                        |     |
|----|------------------------|-----|
| 5. | Symptoms - Other Text: | [ ] |
|----|------------------------|-----|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
SELF

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 28-Mar-2021 02:23

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Health Care Utilization**

|    |                                       |  |
|----|---------------------------------------|--|
| 1. | Physician or Healthcare Professional: |  |
|    | Occurrence of Visits or Contacts:     |  |

**Health Care Utilization Other**

|    |                                     |     |
|----|-------------------------------------|-----|
| 2. | Other Type of Practitioner Specify: | [ ] |
|----|-------------------------------------|-----|

**Health Care Utilization**

|    |  |  |
|----|--|--|
| 3. | Has the subject been hospitalized due to potential COVID-19 illness? |  |
|----|--|--|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Illness Details**

|    |  |  |
|----|--|--|
| 1. | Category of Clinical Event:                              |  |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? |  |
| 3. | Toxicity Grade:  |  |



**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**COVID-19 Illness Visit**

|    |                         |  |
|----|-------------------------|--|
| 3. | COVID-19 Illness Visit: |  |
|----|-------------------------|--|

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB -  
New Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**COVID-19 Repeat Swab**

|    |                       |  |
|----|-----------------------|--|
| 3. | COVID-19 Repeat Swab: |  |
|----|-----------------------|--|

**Header Text:** C4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB -  
New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Not Started

**Site No:** 1223 **Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:30

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit **Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04 **Form Status:** Not Started

**Site No:** 1223 **Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:30

**Unplanned Assessments**

|    |             |  |
|----|-------------|--|
| 1. | Assessments |  |
|----|-------------|--|

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Disposition - Treatment**

|    |   |             |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death : | Nov/6/2020  |
| 2. | Phase of Disposition:                       | VACCINATION |
| 3. | Status:                                     | COMPLETED   |
| 4. | Specify Status:                             | [ ]         |

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |



**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 28-Mar-2021 02:28

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Vital Signs**

|    |       |    |
|----|-------|----|
| 1. | Date: | // |
|----|-------|----|

**Vital Signs Details**

|    |                       |     |
|----|-----------------------|-----|
| 2. | Record Identifier:    |     |
|    | Temperature:          | [ ] |
|    | Unit:                 |     |
|    | Temperature Location: |     |

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Vaccination**

|     |   |     |
|-----|---|-----|
| 1.  | Was there a temporary delay of vaccination?   |     |
| 2.  | Treatment Name  | [ ] |
| 3.  | Formulation:  |     |
| 4.  | Dose Date Time:   | //  |
| 5.  | Anatomical Location:  |     |
| 6.  | Body Side:  |     |
| 7.  | Route:  |     |
| 8.  | Actual Dose:  | [ ] |
| 9.  | Unit:   |     |
| 10. | Timeframe Subject Was Observed  |     |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? |     |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Contact Outcome**

|    |                   |     |
|----|-------------------|-----|
| 1. | Contact Type:     |     |
| 2. | Was contact made? |     |
| 3. | Comments:         | [ ] |

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Contact Outcome**

|    |                   |     |
|----|-------------------|-----|
| 1. | Contact Type:     |     |
| 2. | Was contact made? |     |
| 3. | Comments:         | [ ] |

**Header Text:** C4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** C4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Informed Consent - Asymptomatic Surveillance**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: |  |
|----|--------------|--|

**Header Text:** C4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)



**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Disposition - Follow-Up**

|    |   |     |
|----|---|-----|
| 1. | Date of Completion/Discontinuation /Death : | //  |
| 2. | Phase of Disposition:                       |     |
| 3. | Status:                                     |     |
| 4. | Specify Status:                             | [ ] |

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Dec/22/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Locked, Frozen

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

|    |   |   |
|----|---|---|
| 1. | Select appropriate response - Is participant willing to return for Vaccination 3? | Participant is willing to return for Vaccination 3<br>Participant is:<br>eligible and NOT confirmed to have received only placebo at<br>Vaccination 1/2 |
|----|---|---|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

| #  | Category      | AE Identifier | Adverse Event                 | Start Date        | Is the Adverse Event Still Ongoing | Form Instance                   |
|----|---------------|---------------|-------------------------------|-------------------|------------------------------------|---------------------------------|
| 1. | ADVERSE EVENT | 1             | progression of diverticulitis | Sep/29/2020 13:00 | YES                                | <a href="#">Repeating Pages</a> |
| 2. | ADVERSE EVENT | 2             | Pericolonic Abscesses         | Oct/13/2020 19:00 | YES                                | <a href="#">Repeating Pages</a> |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Not Complete

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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**Adverse Event Report**

|    |   |  |
|----|---|--|
| 1. | Category:   | ADVERSE EVENT  |
| 2. | AE ID:  | [1]  |
| 3. | Adverse Event:<br>(If possible specify diagnosis,<br>not individual symptoms)   | [progression of diverticulitis]  |
| 4. | Start Date Time:  | Sep/29/2020 13:00  |
| 5. | Is the adverse event still ongoing?   | YES  |
| 6. | Toxicity Grade:   | 3  |
| 7. | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?<br/>NO</p> <p>Did this serious event result in death?<br/>NO</p> <p>Did this serious event require or prolong hospitalization?<br/>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?<br/>NO</p> <p>Is this serious event life threatening?<br/>NO</p> <p>Other medically important serious event<br/>NO</p> |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Not Complete

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

|     |   |  |
|-----|---|--|
| 8.  | Is this adverse event the result of a study Medication Error?<br>If Yes, record the type of medication error on the Medication Error Log. | NO   |
| 9.  | Is this event related to study treatment:   | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[History of diverticulitis] |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE   |
| 11. | Was a Concomitant Medication given?   | YES  |
| 12. | Was a Non-Drug Treatment given?   | NO   |
| 13. | What was the outcome of this adverse event?:  | RECOVERING/RESOLVING   |
| 14. | Did the adverse event cause the subject to be discontinued from the study?  | NO   |
| 15. | Serious Adverse Event Number: For Pfizer Use Only   | [2020393225]   |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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**Adverse Event Report**

|    |   |  |
|----|---|--|
| 1. | Category:   | ADVERSE EVENT  |
| 2. | AE ID:  | [2]  |
| 3. | Adverse Event:<br>(If possible specify diagnosis,<br>not individual symptoms)   | [Pericolonic Abscess]  |
| 4. | Start Date Time:  | Oct/13/2020 19:00  |
| 5. | Is the adverse event still ongoing?   | YES  |
| 6. | Toxicity Grade:   | 4  |
| 7. | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?<br/>NO</p> <p>Did this serious event result in death?<br/>NO</p> <p>Did this serious event require or prolong hospitalization?<br/>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?<br/>NO</p> <p>Is this serious event life threatening?<br/>NO</p> <p>Other medically important serious event<br/>NO</p> |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1223**Subject No:** 12231182**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1223) Yale New Haven Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:30

|     |   |   |
|-----|---|---|
| 8.  | Is this adverse event the result of a study Medication Error?<br>If Yes, record the type of medication error on the Medication Error Log. | NO  |
| 9.  | Is this event related to study treatment:   | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[related to an underlying condition reported in Medical History] |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE  |
| 11. | Was a Concomitant Medication given?   | YES   |
| 12. | Was a Non-Drug Treatment given?   | YES   |
| 13. | What was the outcome of this adverse event?:  | NOT RECOVERED/NOT RESOLVED  |
| 14. | Did the adverse event cause the subject to be discontinued from the study?  | NO  |
| 15. | Serious Adverse Event Number: For Pfizer Use Only   | [2020399225]  |



**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

| #  | Category | Medication Error | Start Date | Is the medication error Still Ongoing | Study Medication Errors Action | Form Instance                   |
|----|----------|------------------|------------|---------------------------------------|--------------------------------|---------------------------------|
| 1. |          |                  |            |                                       |                                | <a href="#">Repeating Pages</a> |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

[Back to Form](#)

**Medication Error**

|     |   |     |
|-----|---|-----|
| 1.  | Category:   |     |
| 2.  | Medication Error (Type of Medication Error):                                  | [ ] |
| 3.  | Start Date:   | //  |
| 4.  | Is the medication error still ongoing?  |     |
| 5.  | Latest Action Taken with Study Treatment:                                     |     |
| 6.  | Was a Concomitant Medication given?   |     |
| 7.  | Was a Non-Drug Treatment given?   |     |
| 8.  | Did the Medication Error cause the subject to be discontinued from the study? |     |
| 9.  | Was this medication error associated with any adverse events?                 |     |
| 10. | Serious Adverse Event Number: For Pfizer Use Only                             | [ ] |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

| #  | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Start Date | Form Instance                   |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------|---------------------------------|
| 1. |                            |                         |                                       |                    |            | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**Concomitant Medications**

|    |   |     |
|----|---|-----|
| 1. | What is the medication identifier?  | [ ] |
| 2. | Category:   |     |
| 3. | Concomitant Medications Pre-specified:  |     |
| 4. | Medication:<br><br>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | [ ] |
| 5. | Date:   | //  |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

| #  | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Dose Description | Form Instance                   |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------------|---------------------------------|
| 1. |                            |                         |                                       |                    |                  | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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**Concomitant Medications**

|     |   |     |
|-----|---|-----|
| 1.  | What is the medication identifier?  | [ ] |
| 2.  | Category:   |     |
| 3.  | Concomitant Medications Pre-specified:  |     |
| 4.  | Medication:<br><br>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | [ ] |
| 5.  | Dose:   | [ ] |
| 6.  | Dose Unit:  |     |
| 7.  | Dose Frequency:   |     |
| 8.  | Route:  |     |
| 9.  | Start Date:   | //  |
| 10. | Ongoing?  |     |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

| #  | Category | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Start Date | Form Instance                   |
|----|----------|----------------------|---------------------------------------|-----------|------------|---------------------------------|
| 1. |          |                      |                                       |           |            | <a href="#">Repeating Pages</a> |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

[Back to Form](#)

**Radiation Treatment**

|    |   |     |
|----|---|-----|
| 1. | Category:                                     |     |
| 2. | What is the treatment Identifier?             | [ ] |
| 3. | Concomitant Non-drug Treatment Pre-specified: |     |
| 4. | Treatment:                                    | [ ] |
| 5. | Start Date:                                   | //  |
| 6. | Ongoing?                                      |     |



**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

| #  | Transfusion Type | Date of Transfusion | Form Instance                   |
|----|------------------|---------------------|---------------------------------|
| 1. |                  |                     | <a href="#">Repeating Pages</a> |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

[Back to Form](#)

|    |                      |    |
|----|----------------------|----|
| 1. | Transfusion Type:    |    |
| 2. | Date of Transfusion: | // |

**Header Text:** C4591001

**Visit:**  
UNPLANNED\_BOOSTER\_CONTACT -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** C4591001

**Visit:**  
UNPLANNED\_BOOSTER\_CONTACT -  
Unscheduled

**Form:** BOOSTER DOSE TRIGGER FORM

**Form Version:** 20-Feb-2021 02:20

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Booster Dose Trigger Form**

|    |   |  |
|----|---|--|
| 1. | Select appropriate response -<br>Will the participant return for<br>consent/eligibility assessment<br>for the booster dose visit? |  |
|----|---|--|

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Treatment Unblinded**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded :     | Dec/22/2020                                   |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Withdrawal Of Consent**

|    |                              |    |
|----|------------------------------|----|
| 1. | Withdrawal of Consent Date : | // |
|----|------------------------------|----|

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**Death Details**

|    |   |    |
|----|---|----|
| 1. | Date of Collection / Notification of Death: | // |
|----|---|----|

**Cause of Death**

|    |                        |     |
|----|------------------------|-----|
| 2. | Cause of Death Status: |     |
|    | Cause of Death:        | [ ] |

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Subject Status**

|    |                     |            |
|----|---------------------|------------|
| 1. | Subject Status      | FOLLOW-UP  |
| 2. | Subject Status Date | Nov/6/2020 |



**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[eCRF Audit Trail History](#)

**Casebook Signature Form**

|    |                    |                      |
|----|--------------------|----------------------|
| 1. | Casebook Signature | Click Here to Enable |
|----|--------------------|----------------------|

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

| Name         | Signature Meaning | Date   | Type | Action |
|--------------|-------------------|--|------|--------|
| Jessica Tuan | Approved          | Mar-19-2021 21:15:40 (UTC-05:00)<br>Eastern Time (US & Canada) | BOOK | Signed |

**Affidavit:**

By my dated signature below, I, JessicaTuan, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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| Item | Date   | User                | Comment        |
|------|--|---------------------|----------------|
| Form | Sep-16-2020 18:07:19 (UTC-05:00)<br>Eastern Time (US & Canada) | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001  
**Visit:** Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - Signature History  
**Form Version:** 22-Apr-2020 21:04 **Form Status:** Data Complete, Signed, Verified  
**Site No:** 1223 **Site Name:** (1223) Yale New Haven Medical Center  
**Subject No:** 12231182 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:30

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This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

| Name         | Signature Meaning | Date   | Type | Action |
|--------------|-------------------|--|------|--------|
| Jessica Tuan | Approved          | Mar-19-2021 21:15:40 (UTC-05:00)<br>Eastern Time (US & Canada) | BOOK | Signed |

**Affidavit:**

By my dated signature below, I, JessicaTuan, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

|         |     |  |  |                                   |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Feb-02-2021 12:15:09 (UTC-05:00)<br>Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

**Affidavit:**

N/A

|              |          |  |      |        |
|--------------|----------|--|------|--------|
| Jessica Tuan | Approved | Nov-11-2020 15:16:32 (UTC-05:00)<br>Eastern Time (US & Canada) | BOOK | Signed |
|--------------|----------|--|------|--------|

**Affidavit:**

By my dated signature below, I, JessicaTuan, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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*1. Select appropriate response - Protocol version*

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-16-2020<br>18:06:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>24 JUL 2020 | Initial Entry |

*2. Select appropriate response - What cohort does the subject belong to?*

| Date   | Location        | User                | Value                                 | Reason        |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Sep-16-2020<br>18:06:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>STAGE 3 COHORTS | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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***1. Consent Was:***

| <b>Date</b>  | <b>Location</b> | <b>User</b>         | <b>Value</b>  | <b>Reason</b> |
|--|-----------------|---------------------|---|---------------|
| Sep-16-2020<br>18:06:40<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b><u>Data Entry:</u></b><br>OBTAINED<br>Date Written Consent Ob<br>tained<br><br>Sep/16/2020 | Initial Entry |

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Subject ID**

| Date   | Location        | User                 | Value                          | Reason  |
|--|-----------------|----------------------|--------------------------------|---|
| Oct-29-2020<br>00:11:58<br>(UTC-05:00)<br>Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)     | Query 1: Closed                | event added in ae crf   |
| Oct-28-2020<br>09:13:33<br>(UTC-05:00)<br>Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)     | Query 1: Answered              | Changed data per query  |
| Oct-15-2020<br>06:30:13<br>(UTC-05:00)<br>Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)     | Query 1: Opened                | SAE RECON:AER#2020399225 Pericolonic abscess(onset date:13OCT2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form. |
| Sep-16-2020<br>18:06:18<br>(UTC-05:00)<br>Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>12231182 | Item copied from previous form  |

**2. Birth Date:**

| Date   | Location        | User                 | Value                              | Reason           |
|--|-----------------|----------------------|------------------------------------|------------------|
| Sep-16-2020 18:06:04<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>(b) (6)/1936 | Enrollment Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**3. Sex:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-16-2020<br>18:06:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>MALE | Initial Entry |

**4. Ethnicity:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Sep-16-2020<br>18:06:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT HISPANIC OR LAT<br>INO(A) OR OF SPANISH<br>ORIGIN | Initial Entry |

**5. Race: (Check X all that apply):**

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Sep-16-2020<br>18:06:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>WHITE | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)



**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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*1. Date of Visit*

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-16-2020<br>18:07:11<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sep/16/2020 | Initial Entry |

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Date of Completion/Discontinuation/Death**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-16-2020<br>18:07:46<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sep/16/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-16-2020 18:07:46<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENING | Initial Entry |

**3. Status:**

| Date   | Location        | User                | Value                           | Reason        |
|--|-----------------|---------------------|---------------------------------|---------------|
| Sep-16-2020<br>18:07:46<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231182**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30[Back to Form](#)**1.a**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Sep-16-2020 18:09:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Line/MH Nu 1<br>mber:<br>Medical Histo dislocated sh<br>ry Term: oulder<br>Start Date: UNK/UNK/1<br>966<br>Ongoing: NO<br>End Date:<br><br>UNK/UN<br>K/1967 | Initial Entry |

**1.a Line/MH Number:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-16-2020 18:09:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

**1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date   | Location        | User                           | Value             | Reason                    |
|--|-----------------|--------------------------------|-------------------|---------------------------|
| Oct-28-2020<br>10:48:17<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Giselle<br>Castillo<br>(b) (4) | Query 1: Closed   | Thank you!                |
| Oct-27-2020<br>16:51:55<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)            | Query 1: Answered | Changed data per<br>query |

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1223**Site Name:** (1223) Yale New Haven Medical Center**Subject No:** 12231182**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:30

|  |                 |                                |   |  |
|--|-----------------|--------------------------------|---|--|
| Oct-16-2020<br>11:08:00<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Giselle<br>Castillo<br>(b) (4) | Query 1: Opened                           | Subject has a history of Hypertension, Barrett's esophagitis and GERD recorded on SDB, this is not reflected on Med Hx. Please revise/update accordingly. Thank you. |
| Sep-16-2020<br>18:09:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)            | <b>Data Entry:</b><br>dislocated shoulder | Initial Entry  |

**1.a Start Date:**

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Sep-16-2020<br>18:09:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/1966 | Initial Entry |

**1.a Ongoing:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Sep-16-2020<br>18:09:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>End Date:<br><br>UNK/UNK/1967 | Initial Entry |

**1.b**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

|  |                        |                                 |  |                      |
|--|------------------------|---------------------------------|--|----------------------|
| <p>Sep-16-2020 18:09:54<br/>(UTC-05:00) Eastern<br/>Time (US &amp; Canada)</p> | <p>ACV0PFEINFP6000</p> | <p>auto calc<br/>(autocalc)</p> | <p><b>Data Entry:</b><br/><b>Line/MH Number:</b> 2<br/><b>Medical History Term:</b> atrial fibrillation<br/><b>Start Date:</b> UNK/UNK /1998<br/><b>Ongoing:</b> YES</p> | <p>Initial Entry</p> |
|--|------------------------|---------------------------------|--|----------------------|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231182

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

**1.b Line/MH Number:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Sep-16-2020 18:09:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

**1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date   | Location        | User                | Value                                     | Reason        |
|--|-----------------|---------------------|---|---------------|
| Sep-16-2020 18:09:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>atrial fibrillation | Initial Entry |

**1.b Start Date:**

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Sep-16-2020 18:09:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/1998 | Initial Entry |

**1.b Ongoing:**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-16-2020 18:09:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**1.c**

| Date  | Location        | User                | Value                                   | Reason              |
|---|-----------------|---------------------|---|---------------------|
| Sep-17-2020 13:24:24<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Line/MH Number: 3 | Transcription Error |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

|   |                 |                      |  |               |
|---|-----------------|----------------------|--|---------------|
| Time (US & Canada)  |                 |                      | <b>Medical History Term:</b> sleep apnea<br><b>Start Date:</b> UNK/UNK/2012<br><b>Ongoing:</b> YES   |               |
| Sep-16-2020<br>18:10:36<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 3<br><b>Medical History Term:</b> sleep apnea<br><b>Start Date:</b> UNK/UNK/2012<br><b>Ongoing:</b> YES | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**I.c Line/MH Number:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Sep-16-2020 18:10:36<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

**I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date   | Location                                  | User                        | Value                               | Reason  |
|--|---|-----------------------------|-------------------------------------|---|
| Sep-17-2020 16:13:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS<br>Oracle<br>(b) (4) | Query 1: Closed                     | Discrepancy has been closed.  |
| Sep-17-2020 13:24:24<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000                           | auto query<br>(autoquery)   | Query 1: Answered                   | Transcription Error   |
| Sep-17-2020 13:24:24<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)         | <b>Data Entry:</b><br>: sleep apnea | Transcription Error   |
| Sep-17-2020 01:08:49<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS<br>Oracle<br>(b) (4) | Query 1: Opened                     | Clarify SLEEP APENA as follows...Should spelling be SLEEP APNEA? If so, edit as such or clarify further. Thank you. |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231182

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

|  |                 |                     |                                     |               |
|--|-----------------|---------------------|-------------------------------------|---------------|
| Sep-16-2020<br>18:10:36<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>: sleep apnea | Initial Entry |
|--|-----------------|---------------------|-------------------------------------|---------------|

***1.c Start Date:***

| Date  | Location        | User                | Value                              | Reason        |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-16-2020<br>18:10:36<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2012 | Initial Entry |

***1.c Ongoing:***

| Date  | Location        | User                | Value                     | Reason        |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-16-2020<br>18:10:36<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

***1.d***

| Date   | Location        | User                 | Value   | Reason        |
|--|-----------------|----------------------|---|---------------|
| Sep-16-2020 18:12:01<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 4<br><b>Medical History Term:</b> diverticulitis<br><b>Start Date:</b> UNK/UNK/2019<br><b>Ongoing:</b> YES | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231182

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

**1.d Line/MH Number:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Sep-16-2020 18:12:01<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>4 | Initial Entry |

**1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Sep-16-2020 18:12:01<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>diverticulitis | Initial Entry |

**1.d Start Date:**

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Sep-16-2020 18:12:01<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2019 | Initial Entry |

**1.d Ongoing:**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-16-2020 18:12:01<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**1.e**

| Date   | Location        | User                    | Value                                       | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Oct-27-2020 16:48:03<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Line/MH Num 5<br>ber: | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231182

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

|  |  |  |   |   |
|--|--|--|---|---|
|  |  |  | <b>Medical History Term:</b><br><b>Start Date:</b><br><b>Ongoing:</b> | Hypertension<br>on<br>UNK/UNK/2001<br>YES |
|--|--|--|---|---|

***1.e Line/MH Number:***

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-27-2020 16:48:03<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>5 | Initial Entry |

***1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Oct-27-2020 16:48:03<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Hypertension | Initial Entry |

***1.e Start Date:***

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Oct-27-2020 16:48:03<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2001 | Initial Entry |

***1.e Ongoing:***

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-27-2020 16:48:03<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

*I.f*

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-27-2020 16:48:58<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 6<br><b>Medical History Term:</b> gastroesophageal reflux<br><b>Start Date:</b> UNK/UNK/2001<br><b>Ongoing:</b> YES | Initial Entry |

Header Text: C4591001

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231182

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

***1.f Line/MH Number:***

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-27-2020 16:48:58<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>6 | Initial Entry |

***1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-27-2020 16:48:58<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>gastroesophageal reflux | Initial Entry |

***1.f Start Date:***

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Oct-27-2020 16:48:58<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2001 | Initial Entry |

***1.f Ongoing:***

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-27-2020 16:48:58<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

***1.g***

| Date   | Location        | User                    | Value                                   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Oct-27-2020 16:49:46<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Line/MH Number: 7 | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231182

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Medical History Term:</b> barrett's Esophagitus<br><b>Start Date:</b> UNK/UNK/2017<br><b>Ongoing:</b> YES |  |
|--|--|--|--|--|

***1.g Line/MH Number:***

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-27-2020 16:49:46<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>7 | Initial Entry |

***1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

| Date   | Location        | User                | Value                                       | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-27-2020 16:49:46<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>barrett's Esophagitus | Initial Entry |

***1.g Start Date:***

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Oct-27-2020 16:49:46<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2017 | Initial Entry |

***1.g Ongoing:***

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-27-2020 16:49:46<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

*I.h*

| <b>Date</b>   | <b>Location</b> | <b>User</b>             | <b>Value</b>  | <b>Reason</b> |
|---|-----------------|-------------------------|---|---------------|
| Oct-27-2020 16:51:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH N umber:</b> 8<br><b>Medical His tory Term:</b> Benign Prostat<br>ic Hypertrophy<br><b>Start Date:</b> UNK/UNK/20<br>17<br><b>Ongoing:</b> YES | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**1.h Line/MH Number:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-27-2020 16:51:31<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>8 | Initial Entry |

**1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-27-2020 16:51:31<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Benign Prostatic Hypertrophy | Initial Entry |

**1.h Start Date:**

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Oct-27-2020 16:51:31<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2017 | Initial Entry |

**1.h Ongoing:**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-27-2020 16:51:31<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)



**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:56

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

[Back to Form](#)

**1. Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-16-2020<br>18:13:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sep/16/2020 | Initial Entry |

**2. Weight:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-16-2020<br>18:13:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>78.4 | Initial Entry |

**3. Unit:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-16-2020<br>18:15:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>kg | Initial Entry |

**4. Height:**

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Sep-16-2020<br>18:13:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>169.0 | Initial Entry |

**5. Unit:**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001  
**Visit:** V1\_DAY1\_VAX1\_L **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History  
**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1223 **Site Name:** (1223) Yale New Haven Medical Center  
**Subject No:** 12231182 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:30

|  |                 |                     |                          |               |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-16-2020<br>18:13:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>cm | Initial Entry |
|--|-----------------|---------------------|--------------------------|---------------|

**6. Body Mass Index:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-16-2020 18:15:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>27.5 | Initial Entry |
| Sep-16-2020 18:13:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b>         | Initial Entry |

**7.a**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Sep-16-2020<br>18:13:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 98.1<br><b>Temperature Unit:</b> F<br><b>Temperature Location::</b> ORAL CAVITY | Initial Entry |

**7.a Record Identifier:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-16-2020<br>18:13:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**7.a Temperature:**

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001  
**Visit:** V1\_DAY1\_VAX1\_L **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History  
**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1223 **Site Name:** (1223) Yale New Haven Medical Center  
**Subject No:** 12231182 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:30

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-16-2020<br>18:13:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>98.1 | Initial Entry |

**7.a Unit:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-16-2020<br>18:13:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>F | Initial Entry |

**7.a Temperature Location:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-16-2020<br>18:13:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Randomization Date :**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-16-2020<br>18:14:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sep/16/2020 | Initial Entry |

**2. Randomization Number:**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-16-2020<br>18:14:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>260407 | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-16-2020 18:15:45<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Sep-16-2020 18:15:45<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason   |
|--|-----------------|---------------------------|--------------------|--|
| Sep-17-2020 16:35:53<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed    | Close Auto Query   |
| Sep-17-2020 04:35:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Opened    | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-16-2020 18:15:45<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please                                    |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231182

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

|   |                 |                     |   |                                    |
|---|-----------------|---------------------|---|------------------------------------|
|   |                 |                     |   | review and correct as appropriate. |
| Sep-16-2020<br>18:15:45<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Sep/16/2020 | Initial Entry                      |

5.a

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Sep-17-2020<br>16:35:53<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sample ID: BPXXMJ | Initial Entry |

5.a Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-17-2020<br>16:35:53<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPXXMJ | Initial Entry |

5.b

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Sep-17-2020<br>16:36:25<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sample ID: BPXXMK | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**5.b Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-17-2020<br>16:36:25<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPXXMK | Initial Entry |

**5.c**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Sep-17-2020<br>16:36:45<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPXXML | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-17-2020<br>16:36:45<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPXXML | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-16-2020 18:16:00<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-16-2020 18:16:00<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason   |
|--|-----------------|---------------------------|--------------------|--|
| Sep-17-2020 16:34:07<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed    | Close Auto Query   |
| Sep-17-2020 04:35:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Opened    | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-16-2020 18:16:00<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please                                    |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)



**Header Text:** C4591001  
**Visit:** V1\_DAY1\_VAX1\_L **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1223 **Site Name:** (1223) Yale New Haven Medical Center  
**Subject No:** 12231182 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:30

|   |                 |                     |   |                                    |
|---|-----------------|---------------------|---|------------------------------------|
|   |                 |                     |   | review and correct as appropriate. |
| Sep-16-2020<br>18:16:00<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Sep/16/2020 | Initial Entry                      |

**5.a**

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Sep-17-2020<br>16:34:07<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sample ID: BPXXMH | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-17-2020<br>16:34:07<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPXXMH | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Was there a temporary delay of vaccination?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-16-2020<br>18:16:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-16-2020 18:16:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-16-2020 18:16:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Sep-16-2020<br>18:16:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sep/16/2020 13:36 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-16-2020 18:16:48<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231182

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

|                    |  |  |  |  |
|--------------------|--|--|--|--|
| Time (US & Canada) |  |  |  |  |
|--------------------|--|--|--|--|

6. Body Side:

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-16-2020<br>18:16:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

7. Route:

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-16-2020 18:16:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Sep-16-2020 18:16:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED<br>OBSERVATION PERIOD | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-16-2020<br>18:16:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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*1. Select appropriate response - Reactogenicity diary collection*

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Sep-16-2020<br>18:16:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO - REACTOGENICIT<br>Y E-DIARY NOT COLLE<br>CTED FOR THIS SUBJE<br>CT | Initial Entry |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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*1. Date of Visit*

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-09-2020<br>11:57:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/9/2020 | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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**I. Date:**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-09-2020<br>11:57:49<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/9/2020 | Initial Entry |

**2.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020<br>11:57:49<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier:</b><br><b>Temperature:</b> 97.8<br><b>Temperature Unit:</b><br><b>Temperature Location:</b> FOREHEAD | Initial Entry |

**2.a Record Identifier:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-09-2020<br>11:57:49<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Temperature:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Oct-09-2020<br>11:57:49<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>97.8 | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

**2.a Unit:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-09-2020<br>11:57:49<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>F | Initial Entry |

**2.a Temperature Location:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020<br>11:57:49<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FOREHEAD | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-09-2020 11:58:15<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Oct-09-2020 11:58:15<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason   |
|--|-----------------|---------------------------|--------------------|--|
| Oct-12-2020 12:18:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed    | Close Auto Query   |
| Oct-10-2020 05:20:13<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Opened    | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-09-2020 11:58:15<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please                                    |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)



**Header Text:** C4591001  
**Visit:** V2\_VAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1223 **Site Name:** (1223) Yale New Haven Medical Center  
**Subject No:** 12231182 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:30

|   |                 |                     |  |                                    |
|---|-----------------|---------------------|--|------------------------------------|
|   |                 |                     |  | review and correct as appropriate. |
| Oct-09-2020<br>11:58:15<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Oct/9/2020 | Initial Entry                      |

**5.a**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-12-2020<br>12:18:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPW1NZ | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-12-2020<br>12:18:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPW1NZ | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Was there a temporary delay of vaccination?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020<br>11:59:05<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Oct-09-2020 11:59:05<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Oct-09-2020 11:59:05<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date   | Location        | User                | Value                                  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020<br>11:59:05<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/9/2020 11:03 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Oct-09-2020 11:59:05<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231182

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

|                    |  |  |  |  |
|--------------------|--|--|--|--|
| Time (US & Canada) |  |  |  |  |
|--------------------|--|--|--|--|

6. Body Side:

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Oct-09-2020<br>11:59:05<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

7. Route:

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-09-2020 11:59:05<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-09-2020 11:59:05<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED<br>OBSERVATION PERIOD | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-09-2020<br>11:59:05<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Date of Visit**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-06-2020<br>13:51:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/6/2020 | Initial Entry |

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Nov-06-2020 13:52:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Nov-06-2020 13:52:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason   |
|--|-----------------|---------------------------|--------------------|--|
| Nov-08-2020 10:00:07<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed    | Close Auto Query   |
| Nov-07-2020 02:26:45<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Opened    | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Nov-06-2020 13:52:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please                                    |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231182

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

|   |                 |                     |  |                                    |
|---|-----------------|---------------------|--|------------------------------------|
|   |                 |                     |  | review and correct as appropriate. |
| Nov-06-2020<br>13:52:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Nov/6/2020 | Initial Entry                      |

5.a

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Nov-08-2020<br>10:00:07<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID: BPW1RD</b> | Initial Entry |

5.a Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-08-2020<br>10:00:07<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPW1RD | Initial Entry |

5.b

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Nov-08-2020<br>10:00:20<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID: BPW1RF</b> | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

**5.b Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-08-2020<br>10:00:20<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPW1RF | Initial Entry |

**5.c**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Nov-08-2020<br>10:00:30<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPW1RG | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-08-2020<br>10:00:30<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPW1RG | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Date of Completion/Discontinuation/Death :**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-06-2020<br>13:54:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/6/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Nov-06-2020 13:54:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocale) | <b>Data Entry:</b><br>VACCINATION | Initial Entry |

**3. Status:**

| Date   | Location        | User                | Value                           | Reason        |
|--|-----------------|---------------------|---------------------------------|---------------|
| Nov-06-2020<br>13:54:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)



**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Date of Visit**

| Date   | Location        | User                      | Value                             | Reason   |
|--|-----------------|---------------------------|-----------------------------------|--|
| Feb-16-2021<br>14:01:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Closed                   | Response<br>satisfies query  |
| Feb-16-2021<br>09:19:07<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Answered                 | Transcription<br>Error   |
| Feb-16-2021<br>09:19:07<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b)<br>(4),<br>(b) (6)    | <b>Data Entry:</b><br>Dec/22/2020 | Transcription<br>Error   |
| Feb-04-2021<br>11:58:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Closed                   | Response<br>satisfies query  |
| Feb-03-2021<br>09:22:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)       | Query 2: Opened                   | DM: Kindly<br>review and<br>complete 'Further<br>Vaccination<br>Confirmation'<br>form at this visit.<br>Thank you. |
| Feb-02-2021<br>12:17:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b)<br>(4),<br>(b) (6)    | <b>Data Entry:</b><br>Dec/16/2020 | Transcription<br>Error   |
| Feb-02-2021<br>12:15:09  | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered                 | New Information  |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

|   |                 |                     |                                   |  |
|---|-----------------|---------------------|-----------------------------------|--|
| (UTC-05:00) Eastern Time (US & Canada)                            |                 |                     |                                   |  |
| Feb-02-2021<br>12:15:09<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dec/15/2020 | New Information  |
| Jan-31-2021<br>15:42:00<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened                   | Per source, document, subject contacted site to be unblinded on 16Dec2020. Please clarify if this should be captured here. |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF  
Audit Trail History

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Locked, Frozen

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

| Date  | Location        | User                      | Value  | Reason  |
|---|-----------------|---------------------------|--|---|
| Feb-16-2021<br>09:19:51<br>(UTC-05:00) Eastern<br>Time (US &<br>Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query  |
| Feb-16-2021<br>09:19:23<br>(UTC-05:00) Eastern<br>Time (US &<br>Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date. |
| Feb-16-2021<br>09:19:23<br>(UTC-05:00) Eastern<br>Time (US &<br>Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Participant is willing to return for Vaccination 3<br>Participant is:<br><br>eligible and NOT confirmed to have received only placebo at Vaccination 1/2 | Initial Entry   |

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Oct-09-2020 10:58:02<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1223

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**Form Status:**

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**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

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| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Oct-28-2020 09:12:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231182

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

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**1. Category:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-09-2020 10:58:02<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-09-2020 10:58:02<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date   | Location        | User                      | Value   | Reason                       |
|--|-----------------|---------------------------|---|------------------------------|
| Oct-30-2020 07:04:46<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Closed                                     | Response satisfies query     |
| Oct-29-2020 10:28:33<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered                                   | Changed Information          |
| Oct-29-2020 10:28:33<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>progression of diverticulitis | Changed Information          |
| Oct-29-2020 04:14:25   | ACV0PFEINFP6000 | (b) (6)                   | Query 1: Opened                                     | SAE<br>RECON:AER#2020393225, |

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**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Form Status:** Data Complete, Not Complete

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

|   |                 |                     |   |  |
|---|-----------------|---------------------|---|--|
| (UTC-05:00)<br>Eastern Time (US<br>& Canada)                            |                 | (b) (4)             |   | the event term in SDB was updated to 'progression of diverticulitis' while retained as 'perforated diverticulitis' in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up form. |
| Oct-09-2020<br>10:58:02<br>(UTC-05:00)<br>Eastern Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>perforated divertic<br>ulitus | Initial Entry  |

**4. Start Date Time:**

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-09-2020<br>10:58:02<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sep/29/2020 13:00 | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                | Value                     | Reason                       |
|---|-----------------|---------------------|---------------------------|------------------------------|
| Oct-29-2020<br>10:30:08<br>(UTC-05:00)<br>Eastern Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Transcription Error          |
| Oct-28-2020<br>10:11:07<br>(UTC-05:00)<br>Eastern Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | Query 1: Closed           | Response satisfies<br>query  |
| Oct-28-2020<br>09:09:28   | ACV0PFEINFP6000 | (b) (6)             | Query 1: Answered         | Original value is<br>correct |

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**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1223**Subject No:** 12231182**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Not Complete**Site Name:** (1223) Yale New Haven Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:30

|   |                 |                        |  |   |
|---|-----------------|------------------------|--|---|
| (UTC-05:00)<br>Eastern Time (US<br>& Canada)                            |                 | (b) (4)                |  |   |
| Oct-20-2020<br>13:38:54<br>(UTC-05:00)<br>Eastern Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)    | Query 1: Opened  | ClinQuery: Please<br>clarify if this event<br>had indeed resolved<br>on 5Oct20, as<br>outcome is still<br>noted as<br>recovering/resolving. |
| Oct-09-2020<br>12:04:01<br>(UTC-05:00)<br>Eastern Time (US<br>& Canada) | ACV0PFEINFP6000 | (b)<br>(4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Oct/5/2020 15:00 | New Information   |
| Oct-09-2020<br>10:58:02<br>(UTC-05:00)<br>Eastern Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)    | <b>Data Entry:</b><br>YES  | Initial Entry   |

**6. Toxicity Grade:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-09-2020<br>10:58:02<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>3 | Initial Entry |

**7. Is the adverse event serious?****If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|



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**Site No:** 1223

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**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

|  |                 |                             |                   |  |
|--|-----------------|-----------------------------|-------------------|--|
| Dec-17-2020<br>10:33:10<br>(UTC-05:00)<br>Eastern Time (US & Canada) | ACV0PFEINFP6000 | Giselle Castillo<br>(b) (4) | Query 2: Closed   | Response satisfies query   |
| Dec-16-2020<br>16:18:22<br>(UTC-05:00)<br>Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)         | Query 2: Answered | SAE update submitted with additional symptoms as requested   |
| Nov-30-2020<br>15:04:04<br>(UTC-05:00)<br>Eastern Time (US & Canada) | ACV0PFEINFP6000 | Giselle Castillo<br>(b) (4) | Query 2: Opened   | In the case narrative records final diagnosis for the case. However, initial clinical presentation (symptoms), it is not described. Kindly submit a FU report with this information to be added to the narrative. Thank you. |
| Oct-13-2020<br>05:13:19<br>(UTC-05:00)<br>Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery)      | Query 1: Closed   | Close Auto Query   |
| Oct-11-2020<br>10:00:10<br>(UTC-05:00)<br>Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)            | Query 1: Opened   | SAE RECON: perforated diverticulitus(Onset date:29Sep2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and  |

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**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Not Complete

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

|  |                 |                           |  |   |
|--|-----------------|---------------------------|--|---|
|  |                 |                           |  | report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF   |
| Oct-09-2020<br>10:58:02<br>(UTC-05:00)<br>Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | For AE perforated diverticulitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Oct-09-2020<br>10:58:02<br>(UTC-05:00)<br>Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Is this serious event as sociated with congenital anomaly or birth defect?<br><br>NO<br><br>Did this serious event result in death?<br><br>NO<br><br>Did this serious event require or prolong hospitalization?<br><br>YES<br><br>Did this serious event result in persistent or significant disability/incapacity?<br><br>NO | Initial Entry   |

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|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | Is this serious event life threatening? |  |
|  |  |  | NO                                      |  |
|  |  |  | Other medically important serious event |  |
|  |  |  | NO                                      |  |

**8. Is this adverse event the result of a study Medication Error?  
If Yes, record the type of medication error on the Medication Error Log.**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020<br>10:58:02<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Oct-09-2020<br>10:58:02<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br><br>OTHER<br><br><i>If Other, specify:</i><br><br>History of diverticulitis | Initial Entry |

**10. Latest Action Taken with Study Treatment:**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

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**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

|  |                 |                     |                                      |               |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020<br>10:58:02<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |
|--|-----------------|---------------------|--------------------------------------|---------------|

**11. Was a Concomitant Medication given?**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-09-2020<br>10:58:02<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020<br>10:58:02<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date  | Location        | User                | Value  | Reason                   |
|---|-----------------|---------------------|--|--------------------------|
| Oct-30-2020<br>07:03:37<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | Query 3: Cl<br>osed                                | Response satisfies query |
| Oct-29-2020<br>10:31:48<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>RECOVERI<br>NG/RESOL<br>VING | Changed Information      |
| Oct-29-2020<br>10:30:39<br>(UTC-05:00)<br>Eastern Time                  | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 3: An<br>swered                              | Changed data per query   |

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|   |                 |                           |  |  |
|---|-----------------|---------------------------|--|--|
| (US & Canada)   |                 |                           |  |  |
| Oct-29-2020<br>10:30:08<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Cl<br>osed  | Close Auto Query   |
| Oct-29-2020<br>10:28:33<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Op<br>ened  | For AE progression of diverticulitis:<br>Response to "What was the outcome<br>of this adverse event?" is 'Not<br>Recovered/Not Resolved' but AE<br>End Date/Time is present.   |
| Oct-28-2020<br>04:45:20<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)       | Query 3: Op<br>ened  | SAE<br>RECON:AER#2020393225,outcome<br>was reported as UNKNOWN to<br>Safety DB however, recorded as<br>NOT RECOVERED/NOT<br>RESOLVED on AE CRF. Please<br>confirm correct outcome. If safety<br>update is required, please submit a<br>follow-up form. |
| Oct-27-2020<br>16:44:18<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Op<br>ened  | For AE perforated diverticulitis:<br>Response to "What was the outcome<br>of this adverse event?" is 'Not<br>Recovered/Not Resolved' but AE<br>End Date/Time is present.   |
| Oct-27-2020<br>16:44:18<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Cl<br>osed  | Close Auto Query   |
| Oct-27-2020<br>16:44:18<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>NOT RECO<br>VERED/NO<br>T RESOLV<br>ED | Changed Information  |

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

|   |                 |                           |  |  |
|---|-----------------|---------------------------|--|--|
| Oct-09-2020<br>12:04:01<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Op<br>ened                                | For AE perforated diverticulitus:<br>Response to "What was the outcome<br>of this adverse event?" is<br>'Recovering/Resolving' but AE End<br>Date/Time is present. |
| Oct-09-2020<br>10:58:02<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>RECOVERI<br>NG/RESOL<br>VING | Initial Entry  |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020<br>10:58:02<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**15. Serious Adverse Event Number: For Pfizer Use Only**

| Date  | Location        | User                | Value                            | Reason        |
|---|-----------------|---------------------|----------------------------------|---------------|
| Oct-13-2020 05:13:19<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>2020393225 | Initial Entry |

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Subject Initials: ---

Generated By: (b) (4)

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**1. Category:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-28-2020 09:12:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-28-2020 09:12:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User                | Value                                     | Reason        |
|---|-----------------|---------------------|---|---------------|
| Oct-28-2020<br>09:12:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Pericolonic Abscess | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Oct-28-2020<br>09:12:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/13/2020 19:00 | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date        | Location        | User    | Value           | Reason   |
|-------------|-----------------|---------|-----------------|----------|
| Nov-10-2020 | ACV0PFEINFP6000 | (b) (6) | Query 1: Closed | Response |

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|  |                 |                     |                           |  |
|--|-----------------|---------------------|---------------------------|--|
| 12:16:06<br>(UTC-05:00) Eastern<br>Time (US & Canada)                |                 | (b) (4),<br>(b) (6) |                           | satisfies query  |
| Nov-09-2020<br>17:14:24<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered         | pericolonic<br>abscess is still<br>ongoing.                                      |
| Nov-09-2020<br>15:28:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | Query 1: Opened           | ClinQuery:<br>Please advise on<br>the status, is this<br>event still<br>ongoing? |
| Oct-28-2020<br>09:12:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry  |

**6. Toxicity Grade:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-28-2020<br>09:12:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>4 | Initial Entry |

**7. Is the adverse event serious?****If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

| Date   | Location        | User                      | Value            | Reason              |
|--|-----------------|---------------------------|------------------|---------------------|
| Oct-29-2020<br>00:11:28<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted | Close Auto<br>Query |



Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1223

Subject No: 12231182

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1223) Yale New Haven Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:30

| Time (US & Canada)   |                 |                           |  |  |
|--|-----------------|---------------------------|--|--|
| Oct-28-2020<br>09:12:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | For AE<br>Pericolonic<br>Abscess:<br>Response to "Is<br>the adverse event<br>serious?" is 'Yes'<br>but "Serious<br>Adverse Event<br>Number" is<br>blank. |
| Oct-28-2020<br>09:12:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Is this serious event asso<br>ciated with congenital an<br>omaly or birth defect?<br><br>NO<br><br>Did this serious event res<br>ult in death?<br><br>NO<br><br>Did this serious event re<br>quire or prolong hospital<br>ization?<br><br>YES<br><br>Did this serious event res<br>ult in persistent or signifi<br>cant disability/incapacity<br>?<br><br>NO<br><br>Is this serious event life t<br>hreatening? | Initial Entry  |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1223

Site Name: (1223) Yale New Haven Medical Center

Subject No: 12231182

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:30

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | NO                                      |  |
|  |  |  | Other medically important serious event |  |
|  |  |  | NO                                      |  |

**8. Is this adverse event the result of a study Medication Error?**  
**If Yes, record the type of medication error on the Medication Error Log.**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-28-2020<br>09:12:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-28-2020<br>09:12:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br><br>OTHER<br><br><i>If Other, specify:</i><br><br>related to an underlying condition reported in Medical History | Initial Entry |

**10. Latest Action Taken with Study Treatment:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-28-2020<br>09:12:54<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

|                    |  |  |  |  |
|--------------------|--|--|--|--|
| Time (US & Canada) |  |  |  |  |
|--------------------|--|--|--|--|

**11. Was a Concomitant Medication given?**

| Date  | Location        | User                | Value                     | Reason        |
|---|-----------------|---------------------|---------------------------|---------------|
| Oct-28-2020<br>09:12:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User                | Value                     | Reason        |
|---|-----------------|---------------------|---------------------------|---------------|
| Oct-28-2020<br>09:12:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date  | Location        | User                   | Value   | Reason                   |
|---|-----------------|------------------------|---|--------------------------|
| Oct-30-2020<br>07:07:28<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 1: Closed                                       | Response satisfies query |
| Oct-29-2020<br>10:33:57<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered                                     | Changed Information      |
| Oct-29-2020<br>10:33:57<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)    | <b>Data Entry:</b><br>NOT RECOVERED<br>D/NOT RESOLVED | Changed Information      |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1223

**Subject No:** 12231182

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1223) Yale New Haven Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:30

|   |                 |                     |  |   |
|---|-----------------|---------------------|--|---|
| Oct-29-2020<br>04:03:11<br>(UTC-05:00)<br>Eastern Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | Query 1: Opened                                | SAE<br>RECON:AER#2020393225<br>,outcome was reported as<br>Not recovered/Not resolved<br>to Safety DB<br>however,recorded as NOT<br>RECOVERED/NOT<br>RESOLVED on AE CRF.<br>Please confirm correct<br>outcome.If safety update is<br>required, please submit a<br>ffup form |
| Oct-28-2020<br>09:12:54<br>(UTC-05:00)<br>Eastern Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>RECOVERING/R<br>ESOLVING | Initial Entry   |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-28-2020<br>09:12:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**15. Serious Adverse Event Number: For Pfizer Use Only**

| Date  | Location        | User                | Value                            | Reason        |
|---|-----------------|---------------------|----------------------------------|---------------|
| Oct-29-2020 00:11:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>2020399225 | Initial Entry |

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Date Treatment Unblinded :**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Feb-16-2021<br>09:19:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dec/22/2020 | Initial Entry |

**2. Primary Reason for Unblinding:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Feb-16-2021<br>09:19:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>ASSESS ELIGIBILITY F<br>OR ADDITIONAL VACC<br>INATION | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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**1. Subject Status**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Nov-06-2020 13:54:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP               | Initial Entry |
| Sep-16-2020 18:14:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZE<br>D | Initial Entry |
| Sep-16-2020 18:07:46<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENED                | Initial Entry |

**2. Subject Status Date**

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Nov-06-2020 13:54:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Nov/6/2020  | Initial Entry |
| Sep-16-2020 18:14:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Sep/16/2020 | Initial Entry |
| Sep-16-2020 18:07:46<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Sep/16/2020 | Initial Entry |

090177e196ae301c\Final\Final On: 01-Apr-2021 04:01 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1223

**Site Name:** (1223) Yale New Haven Medical Center

**Subject No:** 12231182

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:30

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*1. Casebook Signature*

| Date  | Location        | User                       | Value                                      | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Nov-11-2020 15:16:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Jessica<br>Tuan<br>(b) (4) | <b>Data Entry:</b><br>Click Here to Enable | Initial Entry |