

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

[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                        | 06 OCT 2020     |
| 2. | Select appropriate response - What cohort does the subject belong to? | STAGE 3 COHORTS |

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Informed Consent**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Oct/22/2020 |
|----|--------------|--|

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** DEMOGRAPHY

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [10051347]                                     |
| 2. | Birth Date:                     | (b) (6)/1961                                   |
| 3. | Sex:                            | FEMALE   |
| 4. | Ethnicity:                      | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE  |
| 6. | Racial Designation:             |  |

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**eCRF Audit Trail History**

**Date of Visit**

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

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Disposition - Screening**

|    |  |             |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death | Oct/22/2020 |
| 2. | Phase of Disposition:                    | SCREENING   |
| 3. | Status:                                  | COMPLETED   |
| 4. | Specify Status:                          | [ ]         |

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Medical History Details**

|     |  |                                 |
|-----|--|---------------------------------|
| 1.a | Line/MH Number:  | [1]                             |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [ENVIRONMENTAL ALLERGIES]       |
|     | Start Date:  | UNK/UNK/1970                    |
|     | Ongoing:   | YES                             |
| 1.b | Line/MH Number:  | [2]                             |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [HIGH BLOOD PRESSURE]           |
|     | Start Date:  | UNK/UNK/1993                    |
|     | Ongoing:   | YES                             |
| 1.c | Line/MH Number:  | [3]                             |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [MENOPAUSE]                     |
|     | Start Date:  | UNK/UNK/2009                    |
|     | Ongoing:   | YES                             |
| 1.d | Line/MH Number:  | [4]                             |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [BREAST LUMPECTOMY]             |
|     | Start Date:  | UNK/UNK/1993                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/1993 |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

|     |  |                                 |
|-----|--|---------------------------------|
| 1.e | Line/MH Number:  | [5]                             |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [CHOLECYSTECTOMY]               |
|     | Start Date:  | UNK/UNK/2018                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/2018 |
| 1.f | Line/MH Number:  | [6]                             |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [BENIGN BREAST FIBROIDS]        |
|     | Start Date:  | UNK/UNK/1993                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/1993 |
| 1.g | Line/MH Number:  | [7]                             |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [UTERINE ABLATION]              |
|     | Start Date:  | UNK/UNK/2008                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/2008 |
| 1.h | Line/MH Number:  | [8]                             |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [GALLSTONES]                    |
|     | Start Date:  | UNK/UNK/2018                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/2018 |

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**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

|     |  |                                 |
|-----|--|---------------------------------|
| 1.i | Line/MH Number:  | [9]                             |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [DYSMENORRHEA]                  |
|     | Start Date:  | UNK/UNK/2008                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/2008 |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** HIV STATUS

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**HIV Status**

|    |   |   |
|----|---|---|
| 1. | Select appropriate response - What is the subject HIV status? | The subject is NOT known to be HIV POSITIVE |
|----|---|---|

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Vital Signs**

|    |                  |             |
|----|------------------|-------------|
| 1. | Date:            | Oct/22/2020 |
| 2. | Weight:          | [156.8]     |
| 3. | Unit:            | LB          |
| 4. | Height:          | [63.0]      |
| 5. | Unit:            | in          |
| 6. | Body Mass Index: | [27.8]      |

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 7.a | Record Identifier:    | 1           |
|     | Temperature:          | [97.5]      |
|     | Unit:                 | F           |
|     | Temperature Location: | ORAL CAVITY |

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**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Oct/22/2020  |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type:                        | URINE        |

**Lab Result**

|     |             |                               |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113]                         |
|     | Test:       | Choriogonadotropin Beta_PX113 |
|     | Result:     |                               |
|     | Not Done:   | NOT DONE                      |

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**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** RANDOMIZATION

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Disposition**

|    |                       |             |
|----|-----------------------|-------------|
| 1. | Randomization Date :  | Oct/22/2020 |
| 2. | Randomization Number: | [272165]    |
| 3. | Randomization Group:  | [ ]         |

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Oct/22/2020 |
| 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 | [BPTZ9Z] |
| 5.b | Sample ID | [BPTZB0] |
| 5.c | Sample ID | [BPTZB1] |
| 5.d | Sample ID | [BJ3W9R] |
| 5.e | Sample ID | [BJ3W9S] |
| 5.f | Sample ID | [BLGDN1] |
| 5.g | Sample ID | [BLGDN2] |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[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/22/2020 |
| 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 | [BPB0HS] |
|-----|-----------|----------|

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**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/22/2020 08:59                         |
| 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                                       |

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**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**eCRF Audit Trail History**

| Date of Visit |                 |             |
|---------------|-----------------|-------------|
| 1.            | Date of Visit   | Nov/12/2020 |
| 2.            | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Nov/12/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 2.a | Record Identifier:    | 1           |
|     | Temperature:          | [97.5]      |
|     | Unit:                 | F           |
|     | Temperature Location: | ORAL CAVITY |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Nov/12/2020  |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type:                        | URINE        |

**Lab Result**

|     |             |                               |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113]                         |
|     | Test:       | Choriogonadotropin Beta_PX113 |
|     | Result:     | NEGATIVE                      |
|     | Not Done:   |                               |

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[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>Nov/12/2020 |
| 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 | [BR62BW] |
|-----|-----------|----------|

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[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:   | Nov/12/2020 16:09                         |
| 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                                       |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**[eCRF Audit Trail History](#)**

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Dec/10/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Dec/10/2020 |
| 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 | [BR627R] |
| 5.b | Sample ID | [BR627S] |
| 5.c | Sample ID | [BR627T] |
| 5.d | Sample ID | [BSMXHC] |
| 5.e | Sample ID | [BSMXHD] |

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**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**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:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**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: | [ ] |
|----|------------------------|-----|

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**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 | [ ] |
|----|-----------|-----|

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**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 | [ ] |
|----|-----------|-----|

**Header Text:** c4591001

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

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**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? |  |
|----|--|--|

**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:** 1005      **Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347      **Subject Initials:** ---

**Generated By:** pfe.levissc      **Generated Time (GMT):** 29-Mar-2021 04:04

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**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 | [ ] |
|----|-----------|-----|



**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**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 | [ ] |
|----|-----------|-----|

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

| #  | Category      | AE Identifier | Adverse Event                   | Start Date          | Is the Adverse Event Still Ongoing              | Form Instance                   |
|----|---------------|---------------|---------------------------------|---------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1             | INJECTION SITE PAIN             | Jan/12/2021 UNK:UNK | NO<br>End Date Time:<br><br>Jan/13/2021 UNK:UNK | <a href="#">Repeating Pages</a> |
| 2. | ADVERSE EVENT | 2             | ENLARGED LYMPH NODE LEFT AXILLA | Jan/12/2021 UNK:UNK | NO<br>End Date Time:<br><br>Jan/26/2021 UNK:UNK | <a href="#">Repeating Pages</a> |
| 3. | ADVERSE EVENT | 3             | CHILLS                          | Jan/12/2021 02:00   | NO<br>End Date Time:<br><br>Jan/12/2021 04:00   | <a href="#">Repeating Pages</a> |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**Adverse Event Report**

|     |   |   |
|-----|---|---|
| 1.  | Category:   | ADVERSE EVENT                               |
| 2.  | AE ID:  | [1]   |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [INJECTION SITE PAIN]                       |
| 4.  | Start Date Time:  | Jan/12/2021 UNK:UNK                         |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Jan/13/2021 UNK:UNK |
| 6.  | Toxicity Grade:   | 1   |
| 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). | NO  |
| 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:   | RELATED                                     |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE                              |
| 11. | Was a Concomitant Medication given?   | NO  |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

|     |  |                    |
|-----|--|--------------------|
| 12. | Was a Non-Drug Treatment given?  | NO                 |
| 13. | What was the outcome of this adverse event?:                               | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO                 |
| 15. | Serious Adverse Event Number:<br>For Pfizer Use Only                       | [ ]                |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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[Form Audit Trail](#)

**Adverse Event Report**

|     |   |   |
|-----|---|---|
| 1.  | Category:   | ADVERSE EVENT                               |
| 2.  | AE ID:  | [2]   |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [ENLARGED LYMPH NODE LEFT AXILLA]           |
| 4.  | Start Date Time:  | Jan/12/2021 UNK:UNK                         |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Jan/26/2021 UNK:UNK |
| 6.  | Toxicity Grade:   | 1   |
| 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). | NO  |
| 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:   | RELATED                                     |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE                              |

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

|     |  |                    |
|-----|--|--------------------|
| 11. | Was a Concomitant Medication given?  | NO                 |
| 12. | Was a Non-Drug Treatment given?  | NO                 |
| 13. | What was the outcome of this adverse event?:                               | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO                 |
| 15. | Serious Adverse Event Number:<br>For Pfizer Use Only                       | [ ]                |

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**Adverse Event Report**

|     |   |   |
|-----|---|---|
| 1.  | Category:   | ADVERSE EVENT                             |
| 2.  | AE ID:  | [3]                                       |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [CHILLS]                                  |
| 4.  | Start Date Time:  | Jan/12/2021 02:00                         |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Jan/12/2021 04:00 |
| 6.  | Toxicity Grade:   | 1   |
| 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). | NO  |
| 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:   | RELATED                                   |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE                            |

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

|     |  |                    |
|-----|--|--------------------|
| 11. | Was a Concomitant Medication given?  | NO                 |
| 12. | Was a Non-Drug Treatment given?  | NO                 |
| 13. | What was the outcome of this adverse event?:                               | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO                 |
| 15. | Serious Adverse Event Number:<br>For Pfizer Use Only                       | [ ]                |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**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:<br>For Pfizer Use Only                          | [ ] |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

| #  | 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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

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**Concomitant Medications**

|    |   |     |
|----|---|-----|
| 1. | What is the medication identifier?  | [ ] |
| 2. | Category:   |     |
| 3. | Concomitant Medications<br>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:   | //  |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

| #  | 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:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**Concomitant Medications**

|     |   |     |
|-----|---|-----|
| 1.  | What is the medication identifier?  | [ ] |
| 2.  | Category:   |     |
| 3.  | Concomitant Medications<br>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?  |     |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**Lab Urinalysis**

|    |                                       |     |
|----|---------------------------------------|-----|
| 1. | Lab Panel:                            |     |
| 2. | Lab Sub-Panel:                        |     |
| 3. | Collection Date:                      | //  |
| 4. | Laboratory Name and Address (Derived) | [ ] |
| 5. | Specimen Type:                        |     |

**Lab Result**

|    |             |     |
|----|-------------|-----|
| 6. | Sponsor ID: | [ ] |
|    | Test:       |     |
|    | Result:     |     |
|    | Not Done:   |     |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**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? |     |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 10-Dec-2020 02:29

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Disposition - Treatment**

|    |  |             |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death : | Dec/10/2020 |
| 2. | Phase of Disposition:                      | VACCINATION |
| 3. | Status:                                    | COMPLETED   |
| 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, Frozen, Verified

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**eCRF Audit Trail History**

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Dec/17/2020 |
| 2. | Erroneous Visit |             |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

[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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 |
|----|---|---|

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**eCRF Audit Trail History**

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Dec/18/2020 |
| 2. | Erroneous Visit |             |



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Dec/18/2020 |
|----|--------------|--|

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

|    |  |                    |
|----|--|--------------------|
| 1. | Date of Completion/Discontinuation/Death : | Dec/18/2020        |
| 2. | Phase of Disposition:                      | REPEAT SCREENING 1 |
| 3. | Status:                                    | COMPLETED          |
| 4. | Specify Status:                            | [ ]                |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Dec/18/2020  |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type:                        | URINE        |

**Lab Result**

|     |             |                               |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113]                         |
|     | Test:       | Choriogonadotropin Beta_PX113 |
|     | Result:     |                               |
|     | Not Done:   | NOT DONE                      |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Dec/18/2020 |
| 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 | [BS32SZ] |
| 5.b | Sample ID | [BS32T0] |
| 5.c | Sample ID | [BRL2JT] |
| 5.d | Sample ID | [BRL2JV] |
| 5.e | Sample ID | [BRL2JW] |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[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>Dec/18/2020 |
| 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 | [BRGWFL] |
|-----|-----------|----------|

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Vaccination**

|     |   |                   |
|-----|---|-------------------|
| 1.  | Was there a temporary delay of vaccination?   | NO                |
| 2.  | Treatment Name  | [BNT162b2]        |
| 3.  | Formulation:  | INJECTION         |
| 4.  | Dose Date Time:   | Dec/18/2020 08:35 |
| 5.  | Anatomical Location:  | DELTOID MUSCLE    |
| 6.  | Body Side:  | LEFT              |
| 7.  | Route:  | INTRAMUSCULAR     |
| 8.  | Actual Dose:  | [30.0]            |
| 9.  | Unit:   | ug                |
| 10. | Timeframe Subject Was Observed  | 30 MINUTES        |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES               |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Treatment Unblinded**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded :     | Dec/17/2020                                   |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**eCRF Audit Trail History**

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jan/11/2021 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Jan/11/2021  |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type:                        | URINE        |

**Lab Result**

|     |             |                               |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113]                         |
|     | Test:       | Choriogonadotropin Beta_PX113 |
|     | Result:     |                               |
|     | Not Done:   | NOT DONE                      |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[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>Jan/11/2021 |
| 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 | [BRF7Z7] |
|-----|-----------|----------|

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Vaccination**

|     |   |                   |
|-----|---|-------------------|
| 1.  | Was there a temporary delay of vaccination?   | NO                |
| 2.  | Treatment Name  | [BNT162b2]        |
| 3.  | Formulation:  | INJECTION         |
| 4.  | Dose Date Time:   | Jan/11/2021 15:58 |
| 5.  | Anatomical Location:  | DELTOID MUSCLE    |
| 6.  | Body Side:  | LEFT              |
| 7.  | Route:  | INTRAMUSCULAR     |
| 8.  | Actual Dose:  | [30.0]            |
| 9.  | Unit:   | ug                |
| 10. | Timeframe Subject Was Observed  | 30 MINUTES        |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES               |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**eCRF Audit Trail History**

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Feb/8/2021 |
| 2. | Erroneous Visit |            |

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** CONTACT OUTCOME

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Contact Outcome**

|    |                   |                                       |
|----|-------------------|---------------------------------------|
| 1. | Contact Type:     | TELEPHONE VISIT                       |
| 2. | Was contact made? | YES<br>Date of Contact:<br>Feb/8/2021 |
| 3. | Comments:         | [ ]                                   |



**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 10-Dec-2020 02:29

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Disposition - Treatment**

|    |  |                      |
|----|--|----------------------|
| 1. | Date of Completion/Discontinuation/Death : | Feb/8/2021           |
| 2. | Phase of Disposition:                      | OPEN LABEL TREATMENT |
| 3. | Status:                                    | COMPLETED            |
| 4. | Specify Status:                            | [ ]                  |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Subject Status**

|    |                     |             |
|----|---------------------|-------------|
| 1. | Subject Status      | FOLLOW-UP   |
| 2. | Subject Status Date | Dec/10/2020 |

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

[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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

[Audit Trail](#)

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

- CRF\_Sign

| Name          | Signature Meaning | Date  | Type | Action |
|---------------|-------------------|---|------|--------|
| Matthew Davis | Approved          | Mar-12-2021 13:43:52 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

**Affidavit:**

By my dated signature below, I, MatthewDavis, 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:** 10-Oct-2020 16:00

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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| Item | Date  | User                             | Comment        |
|------|---|----------------------------------|----------------|
| Form | Oct-22-2020 11:08:30 (UTC-05:00) Eastern Time (US & Canada) | Chelsey LoMonaco (pfe.clomonaco) | Not Applicable |

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

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| Item | Date  | User                             | Comment        |
|------|---|----------------------------------|----------------|
| Form | Dec-21-2020 13:42:35 (UTC-05:00) Eastern Time (US & Canada) | Chelsey LoMonaco (pfe.clomonaco) | 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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

[Back to Form](#)

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

- CRF\_Sign

| Name          | Signature Meaning | Date  | Type | Action |
|---------------|-------------------|---|------|--------|
| Matthew Davis | Approved          | Mar-12-2021 13:43:52 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

**Affidavit:**

By my dated signature below, I, MatthewDavis, 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.

|              |     |   |  |                                   |
|--------------|-----|---|--|-----------------------------------|
| Julie Mooney | N/A | Feb-08-2021 18:14:52 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|--------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|               |          |   |      |        |
|---------------|----------|---|------|--------|
| Matthew Davis | Approved | Jan-21-2021 16:31:09 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, MatthewDavis, 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.

|              |     |   |  |                                   |
|--------------|-----|---|--|-----------------------------------|
| Julie Mooney | N/A | Jan-21-2021 16:30:44 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|--------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

|               |          |   |      |        |
|---------------|----------|---|------|--------|
| Matthew Davis | Approved | Jan-21-2021 16:27:36 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, MatthewDavis, 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:** COHORT\_SELECTION

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Select appropriate response - Protocol version*

| Date  | Location        | User                                   | Value                             | Reason        |
|---|-----------------|--|-----------------------------------|---------------|
| Oct-22-2020 11:05:19<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>06 OCT 2020 | Initial Entry |

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

| Date  | Location        | User                                   | Value                                 | Reason        |
|---|-----------------|--|---------------------------------------|---------------|
| Oct-22-2020 11:05:19<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>STAGE 3 COHORTS | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*I. Consent Was:*

| Date  | Location        | User                                   | Value  | Reason        |
|---|-----------------|--|--|---------------|
| Oct-22-2020 11:05:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtained<br><br>Oct/22/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1005

Subject No: 10051347

Generated By: pfe.lewissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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**1. Subject ID**

| Date  | Location        | User                    | Value                          | Reason                            |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Oct-22-2020 11:05:11<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>10051347 | Item copied from<br>previous form |

**2. Birth Date:**

| Date  | Location        | User                    | Value                              | Reason           |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Oct-22-2020 11:05:08<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>(b) (6)/1961 | Enrollment Entry |

**3. Sex:**

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Oct-22-2020 11:07:39<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>FEMALE | Initial Entry |

**4. Ethnicity:**

| Date  | Location        | User                                   | Value  | Reason        |
|---|-----------------|--|--|---------------|
| Oct-22-2020 11:07:39<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NOT HISPANIC OR LATINO(<br>A) OR OF SPANISH ORIGIN | Initial Entry |

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

| Date  | Location        | User                                   | Value                       | Reason        |
|---|-----------------|--|-----------------------------|---------------|
| Oct-22-2020 11:07:39<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>WHITE | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Date of Visit*

| Date  | Location        | User                                   | Value                                    | Reason        |
|---|-----------------|--|--|---------------|
| Oct-22-2020 11:07:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b><u>Data Entry:</u></b><br>Oct/22/2020 | Initial Entry |



**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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

| Date  | Location        | User                                   | Value                             | Reason        |
|---|-----------------|--|-----------------------------------|---------------|
| Oct-22-2020 11:10:35<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Oct/22/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Oct-22-2020 11:10:35<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        |
|---|-----------------|--|---------------------------------|---------------|
| Oct-22-2020 11:10:35<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051347

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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*1.a*

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Oct-22-2020 11:11:42<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 Hist ENVIRONMENT<br>ory Term: AL ALLERGIES<br>Start Date: UNK/UNK/1970<br>Ongoing: YES | Initial Entry |

*1.a Line/MH Number:*

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-22-2020 11:11:42<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-22-2020 11:11:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>ENVIRONMENTAL ALLERG<br>IES | Initial Entry |

*1.a Start Date:*

| Date  | Location        | User                                   | Value                              | Reason        |
|---|-----------------|--|------------------------------------|---------------|
| Oct-22-2020 11:11:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>UNK/UNK/1970 | Initial Entry |

*1.a Ongoing:*

| Date  | Location        | User                                   | Value                     | Reason        |
|---|-----------------|--|---------------------------|---------------|
| Oct-22-2020 11:11:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051347

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

**I.b**

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-22-2020 11:11:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Line/MH Num 2<br><b>ber:</b><br>Medical Histo HIGH BLOOD P<br>ry Term: RESSURE<br>Start Date: UNK/UNK/1993<br>Ongoing: YES | Initial Entry |

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-22-2020 11:11:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

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

| Date  | Location        | User                                   | Value                                     | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:11:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>HIGH BLOOD PRESSURE | Initial Entry |

**I.b Start Date:**

| Date  | Location        | User                                   | Value                              | Reason        |
|---|-----------------|--|------------------------------------|---------------|
| Oct-22-2020 11:11:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>UNK/UNK/1993 | Initial Entry |

**I.b Ongoing:**

| Date  | Location        | User                                   | Value                     | Reason        |
|---|-----------------|--|---------------------------|---------------|
| Oct-22-2020 11:11:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>YES | Initial Entry |

**I.c**

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

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051347

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

|   |                 |                         |  |               |
|---|-----------------|-------------------------|--|---------------|
| Oct-22-2020 11:13:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number</b> 3<br>:<br><b>Medical History Term:</b> MENOPAUS<br>E<br><b>Start Date:</b> UNK/UNK/2<br>009<br><b>Ongoing:</b> YES | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-22-2020 11:13:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

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

| Date  | Location        | User                                   | Value                           | Reason        |
|---|-----------------|--|---------------------------------|---------------|
| Oct-22-2020 11:13:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>MENOPAUSE | Initial Entry |

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

| Date  | Location        | User                                   | Value                              | Reason        |
|---|-----------------|--|------------------------------------|---------------|
| Oct-22-2020 11:13:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>UNK/UNK/2009 | Initial Entry |

***1.c Ongoing:***

| Date  | Location        | User                                   | Value                     | Reason        |
|---|-----------------|--|---------------------------|---------------|
| Oct-22-2020 11:13:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>YES | Initial Entry |

***1.d***

| Date  | Location        | User                    | Value                                     | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Oct-22-2020 11:15:01<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Nu</b> 4 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

|                    |  |  |  |  |
|--------------------|--|--|--|--|
| Time (US & Canada) |  |  | <b>mber:</b><br><b>Medical History Term:</b> BREAST LUMPECTOMY<br><b>Start Date:</b> UNK/UNK/1993<br><b>Ongoing:</b> NO<br>End Date:<br><br>UNK/UNK/1993 |  |
|--------------------|--|--|--|--|

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

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-22-2020 11:15:01<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        |
|--|-----------------|-------------------------------------|---|---------------|
| Oct-22-2020 11:15:01<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Chelsey LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>BREAST LUMPECTOMY | Initial Entry |

***1.d Start Date:***

| Date   | Location        | User                                | Value                              | Reason        |
|--|-----------------|-------------------------------------|------------------------------------|---------------|
| Oct-22-2020 11:15:01<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Chelsey LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>UNK/UNK/1993 | Initial Entry |

***1.d Ongoing:***

| Date   | Location        | User                                | Value   | Reason        |
|--|-----------------|-------------------------------------|---|---------------|
| Oct-22-2020 11:15:01<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Chelsey LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO<br>End Date:<br><br>UNK/UNK/1993 | Initial Entry |

***1.e***

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

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |                         |  |               |
|---|-----------------|-------------------------|--|---------------|
| Oct-22-2020 11:15:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 5<br><b>Medical History Term:</b> CHOLECYSTECTOMY<br><b>Start Date:</b> UNK/UNK/2018<br><b>Ongoing:</b> NO<br>End Date:<br><br>UNK/UNK/2018 | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1005**Subject No:** 10051347**Generated By:** pfe.levisse**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04***I.e Line/MH Number:***

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-22-2020 11:15:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>5 | Initial Entry |

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

| Date  | Location        | User                                   | Value                                 | Reason   |
|---|-----------------|--|---------------------------------------|--|
| Oct-27-2020 20:46:08<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Lingyan Zuo<br>(pfe.zuo102)            | Query 1: Closed                       | Response satisfies<br>query  |
| Oct-26-2020 10:32:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | Query 1: Answered                     | ADDED<br>CONDITION PER<br>SOURCE   |
| Oct-25-2020 21:39:11<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Lingyan Zuo<br>(pfe.zuo102)            | Query 1: Opened                       | ClinQuery:<br>cholecystectomy:<br>please also record<br>the condition/disease<br>that led to the<br>surgery/procedure<br>being required.<br>Please review and<br>update. |
| Oct-22-2020 11:15:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>CHOLECYSTECTOMY | Initial Entry  |

***I.e Start Date:***

| Date  | Location        | User                                   | Value                              | Reason        |
|---|-----------------|--|------------------------------------|---------------|
| Oct-22-2020 11:15:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>UNK/UNK/2018 | Initial Entry |

***I.e Ongoing:***

| Date  | Location        | User                                   | Value                                 | Reason        |
|---|-----------------|--|---------------------------------------|---------------|
| Oct-22-2020 11:15:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO<br>End Date: | Initial Entry |

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

|  |  |  |              |  |
|--|--|--|--------------|--|
|  |  |  | UNK/UNK/2018 |  |
|--|--|--|--------------|--|

*If*

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-22-2020 11:17:17<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Nu mber:</b> 6<br><b>Medical History Term:</b> BENIGN BREAST FIBROIDS<br><b>Start Date:</b> UNK/UNK/1993<br><b>Ongoing:</b> NO<br>End Date:<br>UNK/UNK/1993 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1005  
**Subject No:** 10051347  
**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1005) Rochester Clinical Research, Inc.  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:04

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-22-2020 11:17:17<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>6 | Initial Entry |

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

| Date  | Location        | User                                   | Value  | Reason        |
|---|-----------------|--|--|---------------|
| Oct-22-2020 11:17:17<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>BENIGN BREAST FIBROIDS | Initial Entry |

***I.f Start Date:***

| Date  | Location        | User                                   | Value                              | Reason        |
|---|-----------------|--|------------------------------------|---------------|
| Oct-22-2020 11:17:17<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>UNK/UNK/1993 | Initial Entry |

***I.f Ongoing:***

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:17:17<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO<br>End Date:<br><br>UNK/UNK/1993 | Initial Entry |

***I.g***

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Oct-22-2020 11:17:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Num</b> 7<br><b>ber:</b><br><b>Medical Histor</b> UTERINE ABL<br><b>y Term:</b> ATION<br><b>Start Date:</b> UNK/UNK/2008 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

|  |  |  |                 |           |  |
|--|--|--|-----------------|-----------|--|
|  |  |  | <b>Ongoing:</b> | NO        |  |
|  |  |  |                 | End Date: |  |
|  |  |  |                 | UNK/UNK/2 |  |
|  |  |  |                 | 008       |  |

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051347

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-22-2020 11:17:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>7 | Initial Entry |

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

| Date  | Location        | User                                   | Value                                  | Reason   |
|---|-----------------|--|--|--|
| Oct-26-2020 14:24:00<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Samuel Dychter<br>(pfe.dychts)         | Query 1: Closed                        | Response satisfies<br>query  |
| Oct-26-2020 10:33:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | Query 1: Answered                      | ADDED<br>CONDITION PER<br>SOURCE   |
| Oct-24-2020 23:45:39<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Samuel Dychter<br>(pfe.dychts)         | Query 1: Opened                        | GPD Clin: Please<br>add to the medical<br>history the<br>pathology that led<br>to the uterine<br>ablation therapy. |
| Oct-22-2020 11:17:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>UTERINE ABLATION | Initial Entry  |

**I.g Start Date:**

| Date  | Location        | User                                   | Value                              | Reason        |
|---|-----------------|--|------------------------------------|---------------|
| Oct-22-2020 11:17:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>UNK/UNK/2008 | Initial Entry |

**I.g Ongoing:**

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:17:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO<br>End Date:<br><br>UNK/UNK/2008 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

*I.h*

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-26-2020 10:32:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 8<br><b>Medical History Term:</b> GALLSTONE<br><b>Start Date:</b> UNK/UNK/2018<br><b>Ongoing:</b> NO<br>End Date:<br>UNK/UNK/2018 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051347

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-26-2020 10:32:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>8 | Initial Entry |

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

| Date  | Location        | User                                   | Value                            | Reason        |
|---|-----------------|--|----------------------------------|---------------|
| Oct-26-2020 10:32:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>GALLSTONES | Initial Entry |

**I.h Start Date:**

| Date  | Location        | User                                   | Value                              | Reason        |
|---|-----------------|--|------------------------------------|---------------|
| Oct-26-2020 10:32:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>UNK/UNK/2018 | Initial Entry |

**I.h Ongoing:**

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-26-2020 10:32:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO<br>End Date:<br><br>UNK/UNK/2018 | Initial Entry |

**I.i**

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-26-2020 10:32:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Numb</b> 9<br><b>er:</b><br><b>Medical History</b> DYSMENORR<br><b>Term:</b> HEA<br><b>Start Date:</b> UNK/UNK/200<br>8 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

|  |  |  |                    |  |
|--|--|--|--------------------|--|
|  |  |  | <b>Ongoing:</b> NO |  |
|  |  |  | End Date:          |  |
|  |  |  | UNK/UNK/<br>2008   |  |

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

| <b>Date</b>   | <b>Location</b> | <b>User</b>             | <b>Value</b>            | <b>Reason</b> |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-26-2020 10:32:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>9 | Initial Entry |

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

| <b>Date</b>   | <b>Location</b> | <b>User</b>                            | <b>Value</b>                       | <b>Reason</b> |
|---|-----------------|--|------------------------------------|---------------|
| Oct-26-2020 10:32:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>DYSMENORRHEA | Initial Entry |

***1.i Start Date:***

| <b>Date</b>   | <b>Location</b> | <b>User</b>                            | <b>Value</b>                       | <b>Reason</b> |
|---|-----------------|--|------------------------------------|---------------|
| Oct-26-2020 10:32:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>UNK/UNK/2008 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1.i Ongoing:*

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-26-2020 10:32:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO<br>End Date:<br><br>UNK/UNK/2008 | Initial Entry |

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** HIV STATUS - eCRF Audit Trail History

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Select appropriate response - What is the subject HIV status?*

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:17:58<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>The subject is NOT known to b<br>e HIV POSITIVE | Initial Entry |



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1005

Subject No: 10051347

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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**1. Date:**

| Date  | Location        | User                                   | Value                             | Reason        |
|---|-----------------|--|-----------------------------------|---------------|
| Oct-22-2020 11:19:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Oct/22/2020 | Initial Entry |

**2. Weight:**

| Date  | Location        | User                                   | Value                       | Reason        |
|---|-----------------|--|-----------------------------|---------------|
| Oct-22-2020 11:19:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>156.8 | Initial Entry |

**3. Unit:**

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Oct-22-2020 11:19:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>LB | Initial Entry |

**4. Height:**

| Date  | Location        | User                                   | Value                      | Reason        |
|---|-----------------|--|----------------------------|---------------|
| Oct-22-2020 11:19:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>63.0 | Initial Entry |

**5. Unit:**

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Oct-22-2020 11:19:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>in | Initial Entry |

**6. Body Mass Index:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-22-2020 11:19:31<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>27.8 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1005

Subject No: 10051347

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

|                    |  |  |  |  |
|--------------------|--|--|--|--|
| Time (US & Canada) |  |  |  |  |
|--------------------|--|--|--|--|

7.a

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:19:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br><b>Record Identifier 1</b><br>:<br><b>Temperature: 97.5</b><br><b>Temperature Unit:</b><br><b>Temperature Location:</b> ORAL CAVITY | Initial Entry |

7.a Record Identifier:

| Date  | Location        | User                                   | Value                   | Reason        |
|---|-----------------|--|-------------------------|---------------|
| Oct-22-2020 11:19:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>1 | Initial Entry |

7.a Temperature:

| Date  | Location        | User                                   | Value                      | Reason        |
|---|-----------------|--|----------------------------|---------------|
| Oct-22-2020 11:19:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>97.5 | Initial Entry |

7.a Unit:

| Date  | Location        | User                                   | Value                   | Reason        |
|---|-----------------|--|-------------------------|---------------|
| Oct-22-2020 11:19:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>F | Initial Entry |

7.a Temperature Location:

| Date  | Location        | User                                   | Value                             | Reason        |
|---|-----------------|--|-----------------------------------|---------------|
| Oct-22-2020 11:19:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:04

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**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Oct-22-2020 11:19:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Oct-22-2020 11:19:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                                   | Value                             | Reason        |
|--|-----------------|--|-----------------------------------|---------------|
| Oct-22-2020 11:19:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Oct/22/2020 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Oct-22-2020 11:19:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>STUDY SITE | Initial Entry |

**5. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Oct-22-2020 11:19:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>URINE | Initial Entry |

**6.a**

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

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

|  |                 |                         |  |               |
|--|-----------------|-------------------------|--|---------------|
| Oct-22-2020 11:19:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 113<br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b><br><b>Not Done::</b> NOT DONE | Initial Entry |
|--|-----------------|-------------------------|--|---------------|

**6.a Sponsor ID:**

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Oct-22-2020 11:19:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

**6.a Test:**

| Date   | Location        | User                                | Value   | Reason        |
|--|-----------------|-------------------------------------|---|---------------|
| Oct-22-2020 11:19:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Chelsey LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX113 | Initial Entry |

**6.a Not Done:**

| Date   | Location        | User                                | Value                          | Reason        |
|--|-----------------|-------------------------------------|--------------------------------|---------------|
| Oct-22-2020 11:19:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Chelsey LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NOT DONE | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Randomization Date :**

| Date  | Location        | User                                   | Value                             | Reason        |
|---|-----------------|--|-----------------------------------|---------------|
| Oct-22-2020 11:21:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Oct/22/2020 | Initial Entry |

**2. Randomization Number:**

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Oct-22-2020 11:21:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>272165 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051347**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-22-2020 11:24:44<br>(UTC-05:00) Eastern<br>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-22-2020 11:24:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                                   | Value   | Reason  |
|---|-----------------|--|---|---|
| Oct-22-2020 11:25:01<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Deleted  | Close Auto Query  |
| Oct-22-2020 11:24:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Oct-22-2020 11:24:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Oct/22/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:25:01<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Sample ID: BPTZ9Z | Initial Entry |

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, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:04

5.a Sample ID

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Oct-22-2020 11:25:01<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BPTZ9Z | Initial Entry |

5.b

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:25:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BPTZB0 | Initial Entry |

5.b Sample ID

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Oct-22-2020 11:25:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BPTZB0 | Initial Entry |

5.c

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:25:16<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BPTZB1 | Initial Entry |

5.c Sample ID

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Oct-22-2020 11:25:16<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BPTZB1 | Initial Entry |

5.d

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:25:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BJ3W9R | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:04

5.d Sample ID

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Oct-22-2020 11:25:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BJ3W9R | Initial Entry |

5.e

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:25:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BJ3W9S | Initial Entry |

5.e Sample ID

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Oct-22-2020 11:25:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BJ3W9S | Initial Entry |

5.f

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:25:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BLGDN1 | Initial Entry |

5.f Sample ID

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Oct-22-2020 11:25:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BLGDN1 | Initial Entry |

5.g

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:26:30<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BLGDN2 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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, Frozen, Verified

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.g Sample ID**

| <b>Date</b>   | <b>Location</b> | <b>User</b>                            | <b>Value</b>                 | <b>Reason</b> |
|---|-----------------|--|------------------------------|---------------|
| Oct-22-2020 11:26:30<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>BLGDN2 | Initial Entry |

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1005**Subject No:** 10051347**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-22-2020 11:26:48<br>(UTC-05:00) Eastern<br>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-22-2020 11:26:48<br>(UTC-05:00) Eastern<br>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-22-2020 11:26:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Deleted  | Close Auto Query  |
| Oct-22-2020 11:26:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Oct-22-2020 11:26:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Oct/22/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Oct-22-2020 11:26:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Sample ID: BPB0HS | Initial Entry |

**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, Frozen, Verified

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.a Sample ID**

| <b>Date</b>   | <b>Location</b> | <b>User</b>                            | <b>Value</b>                 | <b>Reason</b> |
|---|-----------------|--|------------------------------|---------------|
| Oct-22-2020 11:26:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>BPB0HS | Initial Entry |

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051347

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Oct-22-2020 11:20:21<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Oct-22-2020 11:20:21<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-22-2020 11:20:21<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-22-2020 11:20:21<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Oct/22/2020 08:59 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Oct-22-2020 11:20:21<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                | Value                      | Reason        |
|---|-----------------|---------------------|----------------------------|---------------|
| Oct-22-2020 11:20:21<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | Chelsey<br>LoMonaco | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Time (US & Canada) |  | (pfe.clomonaco) |  |
|--------------------|--|-----------------|--|

**7. Route:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-22-2020 11:20:21<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-22-2020 11:20:21<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED O<br>BSERVATION 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-22-2020 11:20:21<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Select appropriate response - Reactogenicity diary collection*

| Date  | Location        | User                                   | Value  | Reason        |
|---|-----------------|--|--|---------------|
| Oct-22-2020 11:21:26<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO - REACTOGENICITY E-D<br>IARY NOT COLLECTED FO<br>R THIS SUBJECT | Initial Entry |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Date of Visit*

| Date  | Location        | User                                   | Value                             | Reason        |
|---|-----------------|--|-----------------------------------|---------------|
| Nov-13-2020 07:14:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Nov/12/2020 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1005

Subject No: 10051347

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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**1. Date:**

| Date  | Location        | User                                   | Value                             | Reason        |
|---|-----------------|--|-----------------------------------|---------------|
| Nov-13-2020 07:15:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Nov/12/2020 | Initial Entry |

**2.a**

| Date  | Location        | User                                   | Value  | Reason        |
|---|-----------------|--|--|---------------|
| Nov-13-2020 07:15:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Record Identifier 1<br>::<br>Temperature: 97.5<br>Temperature Unit:<br>Temperature Location: ORAL CAVITY | Initial Entry |

**2.a Record Identifier:**

| Date  | Location        | User                                   | Value                   | Reason        |
|---|-----------------|--|-------------------------|---------------|
| Nov-13-2020 07:15:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Temperature:**

| Date  | Location        | User                                   | Value                      | Reason        |
|---|-----------------|--|----------------------------|---------------|
| Nov-13-2020 07:15:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>97.5 | Initial Entry |

**2.a Unit:**

| Date  | Location        | User                                   | Value                   | Reason        |
|---|-----------------|--|-------------------------|---------------|
| Nov-13-2020 07:15:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>F | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**2.a Temperature Location:**

| <b>Date</b>   | <b>Location</b> | <b>User</b>                            | <b>Value</b>                      | <b>Reason</b> |
|---|-----------------|--|-----------------------------------|---------------|
| Nov-13-2020 07:15:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:04

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**1. Lab Panel:**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Nov-13-2020 07:15:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Nov-13-2020 07:15:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date  | Location        | User                                   | Value                             | Reason        |
|---|-----------------|--|-----------------------------------|---------------|
| Nov-13-2020 07:15:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Nov/12/2020 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Nov-13-2020 07:15:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>STUDY SITE | Initial Entry |

**5. Specimen Type:**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Nov-13-2020 07:15:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>URINE | Initial Entry |

**6.a**

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

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |                         |  |               |
|---|-----------------|-------------------------|--|---------------|
| Nov-13-2020 07:15:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 113<br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b> NEGATIVE<br><b>Not Done::</b> | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

**6.a Sponsor ID:**

| Date  | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Nov-13-2020 07:15:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

**6.a Test:**

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Nov-13-2020 07:15:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX113 | Initial Entry |

**6.a Result:**

| Date  | Location        | User                                   | Value                          | Reason        |
|---|-----------------|--|--------------------------------|---------------|
| Nov-13-2020 07:15:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NEGATIVE | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1005**Subject No:** 10051347**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-13-2020 07:15:51<br>(UTC-05:00) Eastern<br>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-13-2020 07:15:51<br>(UTC-05:00) Eastern<br>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  |
|---|-----------------|--|---|---|
| Nov-13-2020 07:16:03<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Deleted  | Close Auto Query  |
| Nov-13-2020 07:15:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Nov-13-2020 07:15:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Nov/12/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Nov-13-2020 07:16:03<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Sample ID: BR62BW | Initial Entry |

**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, Frozen, Verified

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.a Sample ID**

| <b>Date</b>   | <b>Location</b> | <b>User</b>                            | <b>Value</b>                 | <b>Reason</b> |
|---|-----------------|--|------------------------------|---------------|
| Nov-13-2020 07:16:03<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>BR62BW | Initial Entry |

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051347

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Nov-13-2020 07:16:40<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Nov-13-2020 07:16:40<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        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Nov-13-2020 07:16:40<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        |
|---|-----------------|--|---|---------------|
| Nov-13-2020 07:16:40<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Nov/12/2020 16:09 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-13-2020 07:16:40<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                | Value                      | Reason        |
|---|-----------------|---------------------|----------------------------|---------------|
| Nov-13-2020 07:16:40<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | Chelsey<br>LoMonaco | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Time (US & Canada) |  | (pfe.clomonaco) |  |
|--------------------|--|-----------------|--|

**7. Route:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-13-2020 07:16:40<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        |
|---|-----------------|-------------------------|---|---------------|
| Nov-13-2020 07:16:40<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED O<br>BSERVATION 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        |
|---|-----------------|--|---------------------------|---------------|
| Nov-13-2020 07:16:40<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Date of Visit*

| Date  | Location        | User                                   | Value                             | Reason   |
|---|-----------------|--|-----------------------------------|--|
| Dec-15-2020 23:29:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Bhumika<br>Prabhu<br>(pfe.prabhb)      | Query 1: Closed                   | Response satisfies<br>query  |
| Dec-15-2020 07:32:19<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Julie Mooney<br>(pfe.jmooney)          | Query 1: Answered                 | completed  |
| Dec-14-2020 04:37:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Amol Shinde<br>(pfe.shinda18)          | Query 1: Opened                   | DM: The treatment<br>period is defined as<br>1st vaccination<br>visit through the<br>1-month post<br>vaccination visit<br>after the 2nd<br>vaccination. Please<br>complete treatment<br>disposition CRF<br>and update date of<br>EOT to match date<br>of visit at visit 3. |
| Dec-11-2020 06:47:53<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Dec/10/2020 | Initial Entry  |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:04

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Dec-11-2020 06:48:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Dec-11-2020 06:48:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                                   | Value   | Reason  |
|---|-----------------|--|---|---|
| Dec-11-2020 06:48:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Deleted  | Close Auto Query  |
| Dec-11-2020 06:48:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Dec-11-2020 06:48:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Dec/10/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-11-2020 06:48:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Sample ID: BR627R | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:04

5.a Sample ID

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Dec-11-2020 06:48:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BR627R | Initial Entry |

5.b

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-11-2020 06:48:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BR627S | Initial Entry |

5.b Sample ID

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Dec-11-2020 06:48:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BR627S | Initial Entry |

5.c

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-11-2020 06:48:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BR627T | Initial Entry |

5.c Sample ID

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Dec-11-2020 06:48:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BR627T | Initial Entry |

5.d

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-11-2020 06:48:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BSMXHC | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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, Frozen, Verified

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.d Sample ID**

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Dec-11-2020 06:48:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>BSMXHC | Initial Entry |

**5.e**

| Date  | Location        | User                                   | Value  | Reason        |
|---|-----------------|--|--|---------------|
| Dec-11-2020 06:48:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br><b>Sample ID:</b> BSMXHD | Initial Entry |

**5.e Sample ID**

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Dec-11-2020 06:48:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>BSMXHD | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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| Date  | Location        | User                                   | Value        | Reason |
|---|-----------------|--|--------------|--------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | Form Created |        |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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| Date  | Location        | User                                   | Value        | Reason |
|---|-----------------|--|--------------|--------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | Form Created |        |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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| Date  | Location        | User                                   | Value        | Reason |
|---|-----------------|--|--------------|--------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | Form Created |        |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051347

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>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        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>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        |
|---|-----------------|--|---|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>INJECTION SITE PAIN | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                                   | Value                                     | Reason        |
|---|-----------------|--|---|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Jan/12/2021 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Jan/13/2021 UNK:UNK | Initial Entry |

**6. Toxicity Grade:**

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

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051347

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

|   |                 |  |                         |               |
|---|-----------------|--|-------------------------|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>1 | 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        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

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        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date  | Location        | User                                   | Value                         | Reason        |
|---|-----------------|--|-------------------------------|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date  | Location        | User                         | Value              | Reason                   |
|---|-----------------|------------------------------|--------------------|--------------------------|
| Feb-26-2021 13:29:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper<br>(pfe.wyperh) | Query 2: Closed    | Response satisfies query |
| Feb-25-2021 15:26:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 2: Answered  | Transcription Error      |
| Feb-25-2021 15:26:57  | ACV0PFEINFP6000 | Julie Mooney                 | <b>Data Entry:</b> | Transcription Error      |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |   |                    |   |
|---|-----------------|---|--------------------|---|
| (UTC-05:00) Eastern Time (US & Canada)                      |                 | (pfe.jmooney)                           | NOT APPLICABLE     |   |
| Feb-18-2021 01:39:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Sathenapalli Suguna Srujan (pfe.srujas) | Query 2: Opened    | CLINQUERY: Please review this entry of 'Drug Withdrawn' for this event that occurred after Vax 4. Since subject has completed the doses on study, this entry does not match with status of subject. |
| Feb-17-2021 10:48:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (pfe.wyperh)               | Query 2: Candidate | CLINQUERY: Please review this entry of 'Drug Withdrawn' for this event that occurred after Vax 4. Since subject has completed the doses on study, this entry does not match with status of subject. |
| Feb-15-2021 09:28:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Erik Sundgaard (pfe.sundgaardea)        | Query 1: Closed    | Response satisfies query  |
| Feb-15-2021 06:46:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Chelsey LoMonaco (pfe.clomonaco)        | Query 1: Answered  | please clarify as this data is correct as entered   |
| Feb-12-2021 07:12:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Roshni Nair (pfe.nairr29)               | Query 1: Opened    | DM: "Latest action taken with study treatment" on AE form is DRUG WITHDRAWN but AE Outcome is not FATAL. Please verify and update the data as appropriate else clarify. Thank you.                  |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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, Frozen

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |  |                                      |               |
|---|-----------------|--|--------------------------------------|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>DRUG WITHDRAWN | Initial Entry |
|---|-----------------|--|--------------------------------------|---------------|

**11. Was a Concomitant Medication given?**

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date  | Location        | User                                   | Value                                    | Reason        |
|---|-----------------|--|--|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>RECOVERED/RESOLVED | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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, Frozen

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:04

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>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        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>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  |
|---|-----------------|---|--|---|
| Feb-17-2021 03:16:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Daria Madar<br>Jacobson<br>(pfe.madard) | Query 1: Closed  | Response satisfies<br>query   |
| Feb-16-2021 13:02:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)               | Query 1: Answered  | Transcription Error   |
| Feb-16-2021 13:02:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Julie Mooney<br>(pfe.jmooney)           | <b>Data Entry:</b><br>ENLARGED LYMPH NODE<br>LEFT AXILLA | Transcription Error   |
| Feb-14-2021 10:33:28<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Daria Madar<br>Jacobson<br>(pfe.madard) | Query 1: Opened  | GPD Clin: Please<br>add to the AE term<br>the anatomical<br>area(s) where the<br>enlarged lymph<br>node occurred. |
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco)  | <b>Data Entry:</b><br>ENLARGED LYMPH NODE                | Initial Entry   |

**4. Start Date Time:**

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051347

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

| Date  | Location        | User                                   | Value                                     | Reason        |
|---|-----------------|--|---|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Jan/12/2021 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Jan/26/2021 UNK:UNK | Initial Entry |

**6. Toxicity Grade:**

| Date  | Location        | User                                   | Value                   | Reason        |
|---|-----------------|--|-------------------------|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>1 | 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        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

**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        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

| Date  | Location        | User                                   | Value                         | Reason        |
|---|-----------------|--|-------------------------------|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>RELATED | Initial Entry |

**10. Latest Action Taken with Study Treatment:**

| Date  | Location        | User                                   | Value                                | Reason        |
|---|-----------------|--|--------------------------------------|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

**11. Was a Concomitant Medication given?**

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date  | Location        | User                                   | Value                                    | Reason        |
|---|-----------------|--|--|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>RECOVERED/RESOLVED | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:44:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:04

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>3 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>CHILLS | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Jan/12/2021 02:00 | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>NO<br>End Date Time:<br>Jan/12/2021 04:00 | Initial Entry |

**6. Toxicity Grade:**

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

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

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| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>1 | 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        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

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        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date  | Location        | User                                   | Value                         | Reason        |
|---|-----------------|--|-------------------------------|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date  | Location        | User                                   | Value                                | Reason        |
|---|-----------------|--|--------------------------------------|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

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

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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, Frozen

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |  |                          |               |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |
|---|-----------------|--|--------------------------|---------------|

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date  | Location        | User                                   | Value                                    | Reason        |
|---|-----------------|--|--|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>RECOVERED/RESOLVED | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Feb-11-2021 05:44:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Form Version:** 10-Dec-2020 02:29

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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

| Date  | Location        | User                          | Value                             | Reason        |
|---|-----------------|-------------------------------|-----------------------------------|---------------|
| Dec-15-2020 07:30:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Julie Mooney<br>(pfe.jmooney) | <b>Data Entry:</b><br>Dec/10/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Dec-15-2020 07:30:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>VACCINATION | Initial Entry |

**3. Status:**

| Date  | Location        | User                          | Value                           | Reason        |
|---|-----------------|-------------------------------|---------------------------------|---------------|
| Dec-15-2020 07:30:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Julie Mooney<br>(pfe.jmooney) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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, Frozen, Verified

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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*I. Date of Visit*

| Date  | Location        | User  | Value                             | Reason  |
|---|-----------------|---|-----------------------------------|---|
| Jan-21-2021 19:35:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Teresa Vu<br>(pfe.vut11)                      | Query 1: Closed                   | Response satisfies<br>query   |
| Jan-21-2021 16:30:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)                     | Query 1: Answered                 | Transcription Error   |
| Jan-21-2021 16:30:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Julie Mooney<br>(pfe.jmooney)                 | <b>Data Entry:</b><br>Dec/17/2020 | Transcription Error   |
| Jan-21-2021 10:21:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Sathenapalli<br>Suguna Srujan<br>(pfe.srujas) | Query 1: Reissued:Opened          | Thanks for the<br>response, form has<br>been unfreeze,<br>please update as per<br>below query |
| Jan-21-2021 08:23:02<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Julie Mooney<br>(pfe.jmooney)                 | Query 1: Answered                 | source provided -<br>please unfreeze this<br>form so date can be<br>updated.                  |
| Jan-19-2021 13:58:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Teresa Vu<br>(pfe.vut11)                      | Query 1: Opened                   | Please provide<br>source and confirm<br>contact date.   |
| Dec-21-2020 13:41:46<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco)        | <b>Data Entry:</b><br>Dec/18/2020 | Initial Entry   |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-21-2020 13:41:58<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Participant is willing to return f<br>or Vaccination 3<br>Participant is:<br><br>eligible per local/national re<br>commendations and confirm<br>ed to have received only pla<br>cebo at Vaccination 1/2 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Date of Visit*

| Date  | Location        | User                                   | Value                             | Reason   |
|---|-----------------|--|-----------------------------------|--|
| Dec-21-2020 13:43:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Closed                   | Close Auto Query   |
| Dec-21-2020 13:42:25<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Opened                   | Date of Visit is<br>before the Date<br>Written Consent<br>Obtained. Please<br>review and update<br>as appropriate. |
| Dec-21-2020 13:42:17<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Dec/18/2020 | Initial Entry  |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF  
Audit Trail History

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**I. Consent Was:**

| Date  | Location        | User                                   | Value  | Reason   |
|---|-----------------|--|--|--|
| Dec-21-2020 13:43:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Closed  | Close Auto Query   |
| Dec-21-2020 13:43:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtain<br>ed<br><br>Dec/18/2020 | Transcription Error  |
| Dec-21-2020 13:42:25<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Opened  | Date Informed<br>Consent Obtained<br>is not the same as<br>the Date of Visit.<br>Please correct as<br>necessary. |
| Dec-21-2020 13:42:25<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtain<br>ed<br><br>Dec/21/2020 | Initial Entry  |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION  
- eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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

| Date  | Location        | User                                   | Value                             | Reason              |
|---|-----------------|--|-----------------------------------|---------------------|
| Dec-21-2020 13:43:00<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Dec/18/2020 | Transcription Error |
| Dec-21-2020 13:42:50<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Dec/21/2020 | Initial Entry       |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                                    | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Dec-21-2020 13:42:50<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>REPEAT SCREENING 1 | Initial Entry |

**3. Status:**

| Date  | Location        | User                                   | Value                           | Reason        |
|---|-----------------|--|---------------------------------|---------------|
| Dec-21-2020 13:42:50<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:04

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**1. Lab Panel:**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Dec-21-2020 13:43:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Dec-21-2020 13:43:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date  | Location        | User                                   | Value                             | Reason        |
|---|-----------------|--|-----------------------------------|---------------|
| Dec-21-2020 13:43:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Dec/18/2020 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Dec-21-2020 13:43:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>STUDY SITE | Initial Entry |

**5. Specimen Type:**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Dec-21-2020 13:43:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINE | Initial Entry |

**6.a**

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

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:23

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |                         |  |               |
|---|-----------------|-------------------------|--|---------------|
| Dec-21-2020 13:43:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 113<br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b><br><b>Not Done::</b> NOT DONE | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

**6.a Sponsor ID:**

| Date  | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Dec-21-2020 13:43:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

**6.a Test:**

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-21-2020 13:43:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX113 | Initial Entry |

**6.a Not Done:**

| Date  | Location        | User                                   | Value                          | Reason        |
|---|-----------------|--|--------------------------------|---------------|
| Dec-21-2020 13:43:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NOT DONE | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)



Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:04

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Dec-22-2020 09:42:25<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Dec-22-2020 09:42:25<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                                   | Value   | Reason  |
|---|-----------------|--|---|---|
| Dec-22-2020 09:42:35<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Deleted  | Close Auto Query  |
| Dec-22-2020 09:42:25<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Dec-22-2020 09:42:25<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Dec/18/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-22-2020 09:42:35<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Sample ID: BS32SZ | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:04

5.a Sample ID

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Dec-22-2020 09:42:35<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BS32SZ | Initial Entry |

5.b

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-22-2020 09:42:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BS32T0 | Initial Entry |

5.b Sample ID

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Dec-22-2020 09:42:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BS32T0 | Initial Entry |

5.c

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-22-2020 09:42:50<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BRL2JT | Initial Entry |

5.c Sample ID

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Dec-22-2020 09:42:50<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BRL2JT | Initial Entry |

5.d

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-22-2020 09:42:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BRL2JV | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.d Sample ID**

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Dec-22-2020 09:42:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BRL2JV | Initial Entry |

**5.e**

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-22-2020 09:43:05<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Sample ID: BRL2JW | Initial Entry |

**5.e Sample ID**

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Dec-22-2020 09:43:05<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>BRL2JW | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form Version:** 22-Apr-2020 21:03**Site No:** 1005**Subject No:** 10051347**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Dec-22-2020 09:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Dec-22-2020 09:43:43<br>(UTC-05:00) Eastern<br>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  |
|---|-----------------|--|---|---|
| Dec-22-2020 09:43:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Deleted  | Close Auto Query  |
| Dec-22-2020 09:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Dec-22-2020 09:43:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Dec/18/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-22-2020 09:43:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Sample ID: BRGWFL | Initial Entry |

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.a Sample ID**

| <b>Date</b>   | <b>Location</b> | <b>User</b>                            | <b>Value</b>                 | <b>Reason</b> |
|---|-----------------|--|------------------------------|---------------|
| Dec-22-2020 09:43:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>BRGWFL | Initial Entry |

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051347

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Dec-21-2020 13:43:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                          | Reason        |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Dec-21-2020 13:43:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BNT162b2 | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Dec-21-2020 13:43:41<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        |
|---|-----------------|--|---|---------------|
| Dec-21-2020 13:43:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Dec/18/2020 08:35 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Dec-21-2020 13:43:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                | Value                      | Reason        |
|---|-----------------|---------------------|----------------------------|---------------|
| Dec-21-2020 13:43:41<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | Chelsey<br>LoMonaco | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051347

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Time (US & Canada) |  | (pfe.clomonaco) |  |
|--------------------|--|-----------------|--|

7. Route:

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Dec-21-2020 13:43:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Dec-21-2020 13:43:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>30.0 | Initial Entry |

9. Unit:

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Dec-21-2020 13:43:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Dec-21-2020 13:43:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>30 MINUTES | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

| Date  | Location        | User                                   | Value                     | Reason        |
|---|-----------------|--|---------------------------|---------------|
| Dec-21-2020 13:43:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>YES | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Date Treatment Unblinded :**

| Date  | Location        | User                                   | Value                             | Reason        |
|---|-----------------|--|-----------------------------------|---------------|
| Dec-21-2020 13:41:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Dec/17/2020 | Initial Entry |

**2. Primary Reason for Unblinding:**

| Date  | Location        | User                                   | Value   | Reason        |
|---|-----------------|--|---|---------------|
| Dec-21-2020 13:41:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>ASSESS ELIGIBILITY FOR A<br>DDITIONAL VACCINATION | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**I. Date of Visit**

| Date   | Location                                  | User                                 | Value                             | Reason   |
|--|---|--------------------------------------|-----------------------------------|--|
| Feb-17-2021<br>09:30:27<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Christian Mayfield<br>(pfe.mayfic01) | Query 1:<br>Closed                | Response<br>satisfies query  |
| Feb-17-2021<br>07:49:45<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Julie Mooney<br>(pfe.jmooney)        | Query 1:<br>Answered              | Visit OOW d/t<br>subject's<br>schedule. Per<br>PI, not IRB<br>reportable.  |
| Feb-17-2021<br>01:21:48<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD<br>(pfe.PFESDQ_PROD)    | Query 1:<br>Opened                | PDQ: Date of<br>visit<br>V102_VAX4 is<br>out of window<br>for 1 days from<br>V101_VAX3<br>Dose Date.<br>Please verify<br>and update.<br>Else, confirm in<br>query response<br>appropriately.<br>"[lv04<br>SDQ=129170]" |
| Jan-12-2021<br>08:21:27<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Chelsey LoMonaco<br>(pfe.clomonaco)  | <b>Data Entry:</b><br>Jan/11/2021 | Initial Entry  |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:04

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**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-12-2021 08:21:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Jan-12-2021 08:21:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                                   | Value                             | Reason        |
|--|-----------------|--|-----------------------------------|---------------|
| Jan-12-2021 08:21:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>Jan/11/2021 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-12-2021 08:21:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>STUDY SITE | Initial Entry |

**5. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Jan-12-2021 08:21:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>URINE | Initial Entry |

**6.a**

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

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:23

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

|  |                 |                         |  |               |
|--|-----------------|-------------------------|--|---------------|
| Jan-12-2021 08:21:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 113<br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b><br><b>Not Done::</b> NOT DONE | Initial Entry |
|--|-----------------|-------------------------|--|---------------|

**6.a Sponsor ID:**

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Jan-12-2021 08:21:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

**6.a Test:**

| Date   | Location        | User                                | Value   | Reason        |
|--|-----------------|-------------------------------------|---|---------------|
| Jan-12-2021 08:21:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Chelsey LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX113 | Initial Entry |

**6.a Not Done:**

| Date   | Location        | User                                | Value                          | Reason        |
|--|-----------------|-------------------------------------|--------------------------------|---------------|
| Jan-12-2021 08:21:48<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Chelsey LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NOT DONE | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** V102\_VAX4**Form Version:** 22-Apr-2020 21:03**Site No:** 1005**Subject No:** 10051347**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-12-2021 08:22:06<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-12-2021 08:22:06<br>(UTC-05:00) Eastern<br>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  |
|---|-----------------|--|---|---|
| Jan-12-2021 08:22:17<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Deleted  | Close Auto Query  |
| Jan-12-2021 08:22:06<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Jan-12-2021 08:22:06<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Jan/11/2021 | Initial Entry   |

**5.a**

| Date  | Location        | User                                   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Jan-12-2021 08:22:17<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Sample ID: BRF7Z7 | Initial Entry |

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.a Sample ID**

| <b>Date</b>   | <b>Location</b> | <b>User</b>                            | <b>Value</b>                 | <b>Reason</b> |
|---|-----------------|--|------------------------------|---------------|
| Jan-12-2021 08:22:17<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>BRF7Z7 | Initial Entry |

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051347

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

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

| Date  | Location        | User                                   | Value                    | Reason        |
|---|-----------------|--|--------------------------|---------------|
| Jan-12-2021 08:22:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                          | Reason        |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Jan-12-2021 08:22:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BNT162b2 | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jan-12-2021 08:22:51<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        |
|---|-----------------|--|---|---------------|
| Jan-12-2021 08:22:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>Jan/11/2021 15:58 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Jan-12-2021 08:22:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                | Value                      | Reason        |
|---|-----------------|---------------------|----------------------------|---------------|
| Jan-12-2021 08:22:51<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | Chelsey<br>LoMonaco | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051347

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:04

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Time (US & Canada) |  | (pfe.clomonaco) |  |
|--------------------|--|-----------------|--|

**7. Route:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-12-2021 08:22:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>INTRAMUSCULAR | Initial Entry |

**8. Actual Dose:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-12-2021 08:22:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>30.0 | Initial Entry |

**9. Unit:**

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Jan-12-2021 08:22:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>ug | Initial Entry |

**10. Timeframe Subject Was Observed**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-12-2021 08:22:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>30 MINUTES | Initial Entry |

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

| Date  | Location        | User                                   | Value                     | Reason        |
|---|-----------------|--|---------------------------|---------------|
| Jan-12-2021 08:22:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <u>Data Entry:</u><br>YES | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Date of Visit*

| Date  | Location        | User                                   | Value                            | Reason   |
|---|-----------------|--|----------------------------------|--|
| Feb-11-2021 14:40:10<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Mina Francisco<br>(pfe.francm73)       | Query 1: Closed                  | Response satisfies<br>query  |
| Feb-11-2021 05:42:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | Query 1: Answered                | updated per request  |
| Feb-09-2021 07:21:53<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Amol Shinde<br>(pfe.shinda18)          | Query 1: Opened                  | DM: Patient<br>completed<br>Vaccination 3 visit<br>through the<br>1-month post<br>vaccination visit<br>after the<br>Vaccination 4.<br>Please complete<br>treatment<br>disposition CRF<br>and update date of<br>EOT2 to match<br>date of visit at visit<br>103. |
| Feb-08-2021 18:14:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Julie Mooney<br>(pfe.jmooney)          | <b>Data Entry:</b><br>Feb/8/2021 | Initial Entry  |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Contact Type:**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Feb-08-2021 18:15:00<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>TELEPHONE VISIT | Initial Entry |

**2. Was contact made?**

| Date  | Location        | User                          | Value   | Reason        |
|---|-----------------|-------------------------------|---|---------------|
| Feb-08-2021 18:15:00<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Julie Mooney<br>(pfe.jmooney) | <b>Data Entry:</b><br>YES<br>Date of Contact:<br><br>Feb/8/2021 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051347**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

| Date   | Location                                  | User                                | Value  | Reason   |
|--|---|-------------------------------------|--|--|
| Feb-12-2021<br>03:09:44<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Pratiksha Mahadik<br>(pfe.mahadp07) | Query<br>1: Clo<br>sed                       | Incorrect Query  |
| Feb-11-2021<br>09:57:50<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(pfe.DMW_QUERY)        | Query<br>1: Op<br>ened                       | DMW7232823;Status<br>on the Disposition -<br>Treatment form is<br>COMPLETED, but<br>Date is different than<br>Visit 3 Date. Please<br>review and update as<br>appropriate. |
| Feb-11-2021<br>05:42:30<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Chelsey LoMonaco<br>(pfe.clomonaco) | <b>Data<br/>Entry</b><br>:<br>Feb/8/<br>2021 | Initial Entry  |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                                      | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Feb-11-2021 05:42:30<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>OPEN LABEL TREATMENT | Initial Entry |

**3. Status:**

| Date  | Location        | User                                   | Value                           | Reason        |
|---|-----------------|--|---------------------------------|---------------|
| Feb-11-2021 05:42:30<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Chelsey<br>LoMonaco<br>(pfe.clomonaco) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051347

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Subject Status**

| Date  | Location        | User                    | Value                                     | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Dec-15-2020 07:30:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP           | Initial Entry |
| Oct-22-2020 11:21:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZED | Initial Entry |
| Oct-22-2020 11:10:35<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        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Dec-15-2020 07:30:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Dec/10/2020 | Initial Entry |
| Oct-22-2020 11:21:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Oct/22/2020 | Initial Entry |
| Oct-22-2020 11:10:35<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Oct/22/2020 | Initial Entry |

090177e196ae2f6c\Final\Final On: 01-Apr-2021 03:43 (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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051347

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Casebook Signature*

| Date  | Location        | User                                 | Value                                      | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Jan-21-2021 10:43:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Liam<br>Sullivan<br>(pfe.lisullivan) | <b>Data Entry:</b><br>Click Here to Enable | Initial Entry |